17

Preparing students for industrial quality control of medicines while keeping a problem-based and research-oriented learning environment

Michael Timm

Department of Pharmacology and Pharmacotherapy, FARMA, University of Copenhagen

Introduction

The MSc education in Pharmacy (Cand. Pharm) at the Faculty of Pharmaceutical Sciences (FARMA), University of Copenhagen, is composed mainly of compulsory courses. Currently, only one semester at the end of the education can be used for elective courses. As a consequence, the elective courses and the final Master's thesis comprise the only specialization the students can obtain within the basic education. Therefore, students that are enrolled in the elective courses have fairly extensive background knowledge and are all (with the possible exception of guest students) at similar academic levels.

The elective FARMA master course "Quality Control of Medicines – microbiological and immunological approaches" (subsequently abbreviated QCM) will have to be transformed from a 5 ECTS intensive course to a 7.5 ECTS block structure course. This will result in a major transformation of the entire course schedule and learning activities. The course was in its original form mainly a laboratory course with focus on methods used for testing medicines for microbial contaminants. The methods used in the course were very diverse and included past, present and future techniques for detection of bacterial contaminants, all with a primary focus on research-based uses.

The transformation of the course in to a block structure requires an intensive restructuring, since the course requires cell culturing and bacterial preparations, processes that should preferably be attended to daily. Since

restructuring is needed, the group of teachers responsible for the course decided that this could represent a golden opportunity to slightly alter the course content to include a more industrial-orientated approach. An initial analysis of the course has helped to identify segments of the course where alignment may be insufficient and where the "Intended Learning Objectives" (ILO), "Teaching/Learning Activities" (TLA) and "Assessment Tasks" (AT) could be improved. It is the overall aim of this work to implement some of the previously identified suggestions for improvement and to evaluate the new course as a whole. The evaluation should include both the teaching group associated with the course (four scientific and two technical administrative staff members) and the students (17 students are enrolled in the course). The new course platform was offered for the first time from November 2010 to January 2011. It was decided by the teaching group associated with the course to make the teaching problem-oriented and to include both techniques and personnel from the industry relevant to the course.

Purpose

This work is conducted in the effort of designing and conducting a course at FARMA that joins:

- Conductance of quality-control experiments of pharmaceuticals according to the currently approved methods for pyrogen testing as used in the industry.
- Independent student work based on "problem-based learning"
- Introduction to novel and research based methods
- Student ability to understand literature within the art, defining problems, preparing protocols for experimentation and apply critical evaluation of results obtained.

It is the overall objective to design the course in a way that appeals to the students so that they find it interesting and relevant, while still keeping the level of education and industrial applicability at an advanced level.

Deliverables

To achieve the overall goal of the project and to obtain valid course evaluation I believe the following nine deliverables are necessary:

- Overall logistical planning of the course determined.

- New course material designed (instruction manuals etc.).
- Revised format for student guidance in the laboratory developed.
- Teaching of the students by research-oriented relevant personal.
- Teaching of the students by industrial relevant personal.
- Student acceptance and consent of the format chosen.
- A questionnaire for student evaluation of the teaching.
- Interview with the teaching group.
- Interview with students.

Success criteria

In order to evaluate the course transformation as a success we believe that it is essential to meet the following success criteria:

- The overall design of the course (the new course material, the logistical planning, the PBL format and the choice of assays) allows industrial and research-based experiments to be conducted along with theoretical considerations, self-reflection and independent study as evaluated by students after the course.
- Students feel that they have a problem-based approach to the questions raised in the course material but still feel that the guidance is adequate. Furthermore, the students' display in-depth topic understanding, can read and understand scientific literature within the field, and have a critical approach to own results which is evident in high marks at the final exam.
- Students are educated in quality control of medicines as conducted in the pharmaceutical industry and novel research methods for quality control of medicines by both scientific and industrial personal. And the students rate the course as relevant both in respect to industrial and scientific research methods and see the connection.
- Interview with teaching group and students, rate the new course as relevant and well-proportioned AND suggests future improvements.

Reflections regarding the teaching format used in QCM

The course in QCM has traditionally been a laboratory focused course. The techniques taught on the course are the cornerstones in the industrial routine testing of medicines. Emphasis has never been on the industrial application of these methods, however, but more related to variants of the tests or alternate applications since this will provide more interesting results in a research and development setting. Moreover, the former curriculum has also

included a variety of alternative tests that are not generally accepted by the authorities or the industry. The reason for this was to provide the students with insight into the research-based approach that we as teachers find fascinating and intriguing. Since this is an elective course, experience teaches us that the participating students are generally enthusiastic and have selected the course on the basis of a true interest in the novel methods we teach. However, only 13% of the students proceed with a research-based career (PhD) while more than 50% will be employed in the medicinal and biotech industry (Farma; 2007). Moreover, since approx. 30% of the postgraduates report that they work with registration, quality assurance or quality control (QA/QC) (Farma; 2007), it is far more likely that a course designed to meet the requirements of the industrial setting would benefit the students more in their future employments.

Education of students is, however, not normally based upon industrial needs or wishes. Nor would it be correct or desirable to exclude the novel methods from the teaching since they comprise the cornerstones of the research-based teaching that may be considered crucial for university studies. However, it could be rightfully argued that students may benefit from both the industrial and the research-based approach to quality control. It is also generally accepted that students will learn more easily if the applicability of the subject is evident.

Traditionally, the format for the course has been the much disputed "cook-book" format where students conduct the experiments according to the instructions of the lab manual. However, unrelated to the format chosen, the whole concept of laboratory teaching has been the subject of many investigations and review papers. In 2005, Hofstein and coworkers summarized many of these reviews by stating that, in general, the research in the area has failed to show simplistic relationships between experiences in the laboratory and student learning (Hofstein et al.; 2005). Hofstein also cites Gunstone & Champagne (1990) for claiming that "learning in the laboratory is possible if students are given ample time and the opportunities for interaction and reflection to initiate discussion" (Hofstein et al.; 2005). In the given setting of the QCM course, it is, however, not only relevant how the conceptual learning of the students is facilitated but also how we can best develop their "craftsmanship skills". The laboratory approach used in the course design is chosen not only to emphasize the theoretical knowledge of the textbook by using follow-up experiments but rather to educate the students in correct practical conductance of experiments. In order to test medicines for minute concentrations of contaminants, it is essential that the

students themselves do not intentionally contaminate the experiments and that they learn to work with outmost precision and overview. This requires that the students are educated in correct techniques and good laboratory practice (GLP) something that can, of course, be studied in a textbook, but never fully comprehended or mastered before bering experienced in a laboratory.

With the obvious need for a hands-on approach to this course, we sought to design the laboratory part of the course based on industrial and regulatory applicability, but with the intention of keeping a research-based problem-oriented approach. Our initial considerations for the course structure is not unlike the one presented by Schulz and McRobbie in a 1994 study regarding a constructivist approach to science experiments (Schulz & McRobbie; 1994). Five major features guided their design of the laboratory teaching:

- Students' own ideas were elicited.
- Students' own ideas clarified/challenged.
- Application activities planned.
- Real life situations used.
- Time and space for student reflection and social interaction.

This study showed a statistically significant increase in learning when employing these major features in the teaching compared with the more traditional laboratory activities.

These major features also reflect some of the considerations we have made in the new design of the QCM course. We want students to play a central role in the design and evaluation of their own experiments while still keeping the industrial and research perspectives in mind. Therefore we have revised all but one exercise in the curriculum to include student planning and in depth evaluation of results.

Course design conceived for QCM

In the newly applied block structure the QCM course is placed in block 2, timetable B. This means that in 2010/2011, the course consisted of five weeks before Christmas break and three weeks after the break where the last week will be reserved for exams.

The general idea for the course design is that the first five weeks are spent in the laboratory and the last two weeks are spent with result evaluation and peer presentations. Furthermore, the last weeks will include orig-

inal literature scrutiny and lectures given by specialists from the industry that are working with quality control on a daily basis.

For the practical part, the students are working together in groups of two. Each group receives two different pharmaceuticals that they are to spend four weeks analyzing using various assays. The last week is spent on a project of the students' own choice.

For the analysis of the original pharmaceuticals, students are not given any instructions apart from the question: "Can these products be released for patient use?" The lab manual describes four Pharmacopoeia-approved methods for microbial quality control (pyrogen tests) whereof we have facilities for conducting three of them and one alternative research-based assay. Basically, the block structure allows each group to have three days of lab time (Monday from 8 to 12, Tuesday from 13 to 17 and Friday from 8to 12) for each test and three days for an independent project.

Without the students' knowledge, the original drug products are divided between the groups in such a way that each group will receive one product which has been intentionally contaminated with microbial debris and one product that due to its formulation exerts interference with one or several of the assays.

It is, thus, the objective of the students to overcome the interference of one product and to correctly identify the contaminated product in relation to origin of the contaminant and the concentration of the contaminant.

It is intended that on the first day the students familiarize themselves with the new test and test their products s according to the general description from the lab manual. When they then experience the possible problems of testing some products directly (due to interference), they are to use the second day to refer to literature and to conceive ideas to overcome potential problems. On the third day, the students can repeat the experiment implementing their own conceived experimental designs. Students can, of course, utilize the experiences from the previous experiment in the next, and thereby increase the possibility of correctly identifying the origin and concentration of the contaminant.

If we were to relate the herein described course design to the five features described by Schulz & McRobbie (1994), we could relate the content to the five features in the following way:

> It is the overall idea that the students must conceive a way to get rid of the interfering substances in the medicines; furthermore students will have to adapt the experimental design of product testing in a way so that it will fulfil the requirements of the pharmacopoeia.

Based on the results of the first experiments, students' ideas to eliminate interference or improve detection limits will be discussed/validated with the teachers in order to verify that all relevant controls have been included and that the chosen format fulfils requirements. If not, students are encouraged to change the experimental design. (It should be noted that there are no teacher comments in regard to whether or not the experimental set-up will give the results intended. It is likely that the setup chosen by the students will not provide the desired results, this is however also considered a "positive/successful" outcome of the exercise).
Application activities planned in relation to above mentioned.
Similar to an industrial setting, the exercises are conducted as teamwork with the possibility of peer discussions. Real pharmaceuticals are used and the experiments are conducted more or less as they would have been conducted in an industrial quality control laboratory. Furthermore, the students have the overall (imaginary) responsibility for whether or not the product can be released to patients, an obligation that is identical to the one they will face in a future position in a QC laboratory.
Students will have ample time to discuss the results and future approaches on day two of an experiment. Furthermore, four groups of students will be working with the same technique and thus have time for joint reflection and social interaction throughout the days. At the end of the course, the two weeks of classroom teaching will include group work with opponent group discussion and peer presentation of the experimental design chosen and results obtained.

Considerations regarding the good PBL student and the good PBL facilitator

At FARMA, PBL or other variants of the minimally guided approach have been implemented for several years. The current use of PBL is highly dependent on the course and course director, but many compulsory as well as elective courses have PBL exercises included. If we look at the general characteristics of PBL, namely, that: (81) Learning is driven by challenging, open-ended, ill-defined and ill-structured problems. (2) Students generally work in collaborative groups, and (3) Teachers take on the role as "facilitators" of learning. One could argue that what some teachers consider PBL might be far away from this definition. The laboratory setting seldom supports truly open-ended, ill-defined and ill-structured problems since the equipment will always limit the possible ways and means of solving a problem. Moreover, it seems that even though teachers try to take the

role as facilitators, most teachers who attempt to implement a constructivist approach end up providing students with considerable guidance (Kirschner et al.; 2006).

It is the overall aim to adapt a PBL-like format to the QCM course since the teaching group believes that the problem-based approach will encourage the students to undertake an indepth investigation in regard to the application and value of the various methods, while still focusing on the importance of learning the craftsmanship related to the techniques. With this in mind, it is highly relevant to consider how we can best facilitate a PBL-like approach to the course. One of the key aspects is to make students aware of the format and to let them know what is expected of them. Here we emphasize the fact that the students are given ample time to conduct the experiments since we expect that many students will find this format confusing and frustrating in the beginning due to the lack of guidance and poor prerequisites of the students. Likewise, the instructors have to adapt to the role of facilitators instead of teachers. This process is also expected to pose a considerable challenge.

Recognizing that it may serve little purpose discussing whether or not a laboratory course can ever fully fulfil the general characteristics of PBL, it may perhaps be more useful to look at the openness of the course. Using the four levels of enquiry (0: Confirmation/Verification, 1: Structured Inquiry, 2: Guided Inquiry and 3: Open Inquiry) we may be able to evaluate the degree of openness of the various exercises according to the Schwab/Herron levels of laboratory openness (Fig. 17.1).

LEVEL	PROBLEM	WAYS & MEANS	ANSWERS
0	Given	Given	Given
1	Given	Given	Open
2	Given	Open	Open
3	Open	Open	Open

Fig. 17.1. Schwab/Herron Levels of Laboratory Openness

The classic cookbook experiment would normally represent level 0 or 1 whereas the fully implemented PBL project would be a level 2 or 3 exercise.

Implementing the decided changes in QCM would result in a course structure allowing students to work with “one project”. The objective is to verify whether or not two selected products can be released for patient

use. The implementation of this project-based structure meant that we had to eliminate a few classical cookbook exercises and include a new method that was well defined in literature. Thus, the execution of the individual tests was still subjected to well-described protocols, but the format would have to be defined and altered based on the literature discovered by the students. This way, the otherwise well-defined problem with given ways or means, was now much more open-ended and allowed student speculation regarding assay setup and sample preparation. Therefore, compiling three or four classical cookbook experiments to one project both increased the level of openness and introduced a problem-oriented approach to QC problems much like the students are expected to encounter in their future professional careers. It is the intention that the Schwab/Herron model for laboratory openness should be kept in mind when advising the students and that this may support the transformation from "teacher/instructor" to "facilitator".

We, therefore, believe that the PBL-based approach fully supports the considerations we have made regarding the course. It is, however, an essential prerequisite that both students and instructors are fully aware of the requirements and limitations of the format.

Assessment

The course was originally assessed by an oral examination and it was early on decided to keep this format. It is, generally, believed by the teaching group that this allows more indepth discussions regarding choice of assays for quality control as well as supporting the possibility of student to relate critically to their own results obtained in the projects with greater detail and nuance. This examination form is believed to be well suited for the course since the key learning objectives are to conduct and to account for the theoretical aspects of a given method, but more importantly to assess the value and the results of an applied method to a given problem.

One problem in regard to this assessment format is that it does not take directly into account the ILOs related to the laboratory work. In the "course outcome", as defined by the course description point seven states that students should be able to conduct Quality Control as described by Regulatory Authorities. However, the practical experimental skills are not directly assessed in the final exam. It could be argued that the laboratory performance of the students is indirectly evaluated since the results obtained in the labo-

ratory form the basis of their further reflections and evaluation. It is likely that the assessment format could take reflections done in the laboratory into account and results obtained to an even greater extend. One way would be to include an assessment of the final "quality control (QC) report" the students are to submit. This assessment could then count for a percentage of the grade. However, since the "QC report" is the final result of weeks of group work, assigning a mark to the report would require the students to list a responsible person for each section of the report (due to the Danish legislation regarding group examinations) and this division of tasks and responsibility between group members is not believed to benefit the overall objective of the course. Therefore, we decided to base the entire evaluation on the final oral examination.

One interesting alternative would be to make a final individual one-week project based on full implementation of the PBL format where students could harvest the experiences obtained in the foregoing weeks. This experiment could then result in an individual report that is evaluated by the seven-scale grading system constituting e.g. 30-50% of the final grade. This suggested evaluation form should allow students to perceive that their performance in the laboratory as well as their analytical and problem-solving skills are evaluated and thus improve the alignment of the course. Unfortunately, the limitations in available laboratory equipment preclude this possibility.

For the exam, the limited information in the lab manual, the QC report and all original literature presented during the course constitute the curriculum.

Results

Implementation of the new course structure in the laboratory part

With some obstacles, the overall logistical planning of the course was comprised in a way that allowed transition from intensive course to block structure course. Especially, the continuous cultivation of cells represented a challenge but the goodwill and flexibility of the technical staff associated with the course allowed the five weeks of laboratory work to be conducted in an orderly and meaningful way. However, limitations in the apparatus available did suggest that precautions may be relevant with a fully booked course (24 students instead of the 17 we had enrolled this year). It is the

general impression from the teaching group that the new course material designed was suited for the purpose and that the high degree of openness did not intimidate the students. General discussions in the teaching group also revealed a common agreement that the aim to implement a constructive approach was, in part, successful and we believed that the direct guidance of the students was kept to a minimum. There was a general acceptance of students' ideas that were "outside the box" and students were in general encouraged to proceed with experiments even though the apparent chances of success were minimal. In cases where intervention was required, the help was generally related to literature referral. It was also the general conclusions of the teaching group that the increased focus on problem solving did not affect the technical conductance of experiments. It was, therefore, the general impression that the revised format for student guidance in the laboratory was successfully applied.

Observations done during the course

Based on the experiences from the past five years of lecturing this course, some changes in student behavior were evident. The following section is based on own subjective observations but all observations has been discussed with the teaching group and general consensus was achieved in relation to the following statements.

"The students were calm".
It was the general expectation from the teaching group that the very open format would confuse and frustrate some students. Eventually, this could mean that students would feel discouraged or stressed by not knowing which expectations to meet. This was, however, not the case. All students embraced the challenge in a calm and orderly fashion and they conceived and executed the experiments with high dedication.
"The students used the experiences from former experiments without any teacher encouragement".
Without any teacher involvement students immediately linked the different exercises and transferred the experiences obtained in one experiment to the planning of the next.
"It was the general opinion from the teacher group that the students were better prepared this year compared to last year".
The students seemed well-prepared and had read the sparse information in the lab manual and most had prepared individual notes and calculation for the experiments to be undertaken.

> *"Students struggle to relate obtained results to real life settings and sometimes lose faith in the validity of their results, their own capabilities and/or the overall aim"*.
> Even though we as instructors take great effort in stressing that this course is based on methods as applied in the pharmaceutical industry we would still get asked: "How do they do this in the industry" and when we reply "This way" we were in part met with disbelief. Furthermore, students did not fully comprehend that problem-solving skills should be learned during this course, so a general reply to the student statement: "But it's impossible to do it like this" quickly became: "then come up with a solution. . . or go tell the boss that he will have to throw away a product worth 20 million because you do not know how to analyze it. . . " However, eventually the students understood the format and the statement "If you can't do it the right way, do it another way. . . " became accepted as indicative that not all solutions are described in literature and that it is better to try and to fail than not to try. Hereafter, the quest for results was well undertaken by all students.

Furthermore, it was the general perception of the teaching group that we maintained a non-threatening environment in which the students thrived even though student-teacher interactions were sometimes retained at a minimum.

Student evaluation of the course structure as applied in the laboratory

At the end of the laboratory part of the course, students were asked to give an oral evaluation of the course based on their experiences in the laboratory.

In regard to the planning and execution of the practical part of the course, the comments from the students reflected a general appreciation of the format with important suggestions for alterations.

The students believed that there was ample time for the experiments and appreciated that they could plan their own time in the lab. This included that they could fill in the gaps between experimentation or while waiting for results with planning of the next experiment or literature scrutiny.
Student comment: "It's good that we have so much time for the exercises, otherwise it would be very frustrating not knowing what to do in the exercises"
Student comment: "We can spend the time reasonably while we are here"
Students also liked that they could repeat some of the exercises, if necessary.

Student comment: "It's good with the repetition of an experiment, the purpose became clearer."

All students agreed that it was an advantage that we apply industrial relevant experiments in the course and would prefer an increased focus on the final QC report.

The students argued that they would have liked some more theory to begin with before entering the laboratory. However, when asked, most agreed that it is more valuable to have a "hands on" experience with the assay before applying theoretical considerations. A feasible alternative was suggested by one of the students that waiting time occasionally associated with an exercise could, to a greater extent, be used constructively for student-teacher interactions regarding the related theory. With regard to non-exercise related theory, it has, however, always been the intention of the teaching group to begin the course with a general theoretical session to get students on the "right track" from the beginning. But for logistical reasons, we had to start with the laboratory exercises from day one of the course.

Another related request of the students was that more literature should be made available beforehand for preparations. I believe that this request could be interpreted in several ways. An obvious (and perhaps convenient) interpretation would be that the students are highly dedicated and want to learn more. Another less flattering interpretation could be that the students are uncomfortable with the problem-based approach and that they prefer some guidance in their literature search confining the possibilities to formulate their own project. However, with due respect to the fact that the students are presented to a new area of expertise with a different set of tools than they are use to, I chose to interpret this request as reasonable wish to be guided in the right direction before major considerations regarding assay designs are discussed amongst group members.

Contradictory to our general beliefs, the students did not perceive the limited student-teacher interactions as positive. We were under the impression that the students liked our distant approach so they would have a chance to discuss general issues amongst themselves without teacher involvement. However, according to student statements they felt that we as teachers tended to situate ourselves in a group away from the students, making us more unapproachable for questions and discussions. This observation is regarded as very important since it represents a problem without any obvious solution. We can easily recognize that we did situate ourselves away from the students but for the sole reason of letting the students work

independently. But if the students in any way feel that we are unapproachable in these situations, we may be facing a problem with the format. It is the obvious suggestion that we in the future are in closer proximity to the students and try to keep teacher-teacher discussions to a minimum. However, this must not affect the independence and lively discussions amongst students.

Implementation of the new course structure in the theoretical part

The two weeks of the course spent outside the lab was divided between:

- Group work (completion of reports, preparation of presentations, and general discussions).
- Discussions with opponents (time was reserved for discussion of findings and how challenges were overcome by the different groups, we hoped that this would provide a forum for knowledge transfer).
- Lectures by teachers (a theoretical walk-through of the different techniques used during the course).
- Presentation from QC professionals (from Novo Nordisk and CMC biological) mainly centered around how the QC tests we used in the laboratory are conducted on a routine basis and how the results affects their daily work.
- Student presentations (QC report findings, theory and results from their self designed project and presentation of original literature.

In general, the teaching group had little involvement in the group work and discussions with opponent groups and thus, did not get a good feeling as to how the time was spent. The lectures seemed to interest the students and basis for good discussions was formed. Likewise the presentation from the QC professionals seemed to interest the students and the consensus between the daily work of a QC professional and the tests that we had worked with, further validated the relevance of the course. We also found the student presentation to be of a fairly high quality and they were, in general, well-structured and comprehensive. The subsequent discussions were, therefore, fruitful and interesting. We felt that the students had spent the majority of their time on findings from the QC report and this was interpreted as sincere student interest in the project. One downside to this was, however, that it became somewhat one-sided to hear the results of eight fairly similar projects which also seemed to bother the students.

The final course evaluation was done by a student evaluation form as shown below where the results are included.

Student evaluation form for Quality Control of Medicines –microbiological and immunological approaches, Jan 2011

Dear Student!
Your input is very important in order for us to prioritize which educational aspects of our courses should be improved. Therefore, we kindly ask you to fill in this form. Your responses will be anonymous. The overall results will be used by the lecturers and the Teaching Committee of this institute to improve the quality of our courses – and we thus appreciate your sincere and constructive feedback.
Yours sincerely,
Erik Wind Hansen, Lise Moesby and Michael Timm
Name of course: Quality Control of Medicines

Course Objectives: To give students the opportunity to learn, evaluate and conduct Quality Control of medicines using a microbiological and immunological approach. The methods described in Ph.Eur. and other regulatory authorities are addressed.

Please indicate with an 'X' the answer that best represents your opinion (only one 'X' per row)	1 Strongly agree	2 Agree	3 Neutral	4 Disagree	5 Strongly disagree	Don't know
I experienced a good correspondence between the teaching and the course objectives (as indicated above)	2	13	2			
I think that the practical execution of the course was successful (facilities, equipment, information dissemination etc.)	2	10	3	1		1
I experience a good coherence between the various course elements (lectures, practical work, etc.)		10	6	1		
I experience the course as relevant to my personal educational objectives	7	8	1			1
In cases where I needed feedback on my work (presentations, assignments, papers, reports) I was able to adequately get such feedback from the teachers	7	8	1			1
For me, the teaching material is adequate for this course.	1	5	6	4	1	
I liked that the course was relevant for quality control in the industrial setting	10	7				
I preferred the problem orientated approach to the subject over the traditional laboratory course approach	2	10	5			

Compared to my background knowledge I experience that the academic level of the course is:					
1 Far too low	2 Low	3 (16) Adequate	4 (1) High	5 Far too high	Don't know

I experience the work load of the course as:					
1 Much too low	2 (4)* Somewhat low	3 (10) Adequate	4 (6)* Somewhat high	5 Much too high	Don't know

*some responders had marked both 2 and 4 as an option indicating that the work load was somewhat low in the fall and somewhat high after the Christmas break

7.5 ECTS-points: In this course, for me the average work load per week was (including classes, preparation, written assignments etc.):					
1 Under 10 hours	2 10-15 hours (3)	3 15-20 hours (12)	4 20-25 hours (4)	5 25-30 hours	6 Over 30 hours (1)

List three things that should be kept in the course next year

I have listed the statements by the students in a slightly categorized and reduced form and listed the number of students having supported the statement:

The QC report (6)
Oral presentations by the students (6)
That we centered the course around test with an industrial applicability (5)
That the same products were tested repeatedly by various tests (5)
Exercise D (the student designed project) (5)
The high number of teachers associated to the course (4).
Use of scientific papers (3)
The order of which we conducted the lab/seminars (2)
Lectures by the teachers (2)
Lectures by QC professionals (2)
The Lab manual (2)
Working with "real life" problems (1)
The general good vibe in the laboratorium (1)

List three things that should be changed in the course next year and indicate how!

I have listed the statements by the students in a slightly categorized and reduced form and listed the number of students having supported the statement:

Distribution of the work load; before/after the Christmas break (8)
More theory (primarily in the context of general immunology and introduction to excercises (8)
Clear curriculum definition from the start (5)
Use lab pauses more efficiently (4)
More communication via absalon (4)
Communication between teachers and students regarding the preparation of the QC report (3)
More information regarding the exam (3)
Not necessary to hear all QC reports presented (2)
More mixing of theory and experiments (2)
Too much time for group work (2)
Student abstracts from the scientific papers should be edited/approved by teachers before distribution (1)
More structure (1)
Teachers should have encouraged more to general discussions (1)

Analysis of student evaluation form

In general, the evaluation form is fairly consistent with the observations done by the teachers and the comments made by the students in the oral evaluation of the laboratory part.

We deduce from question 1-5 that the students, in general (with only a few exceptions), find that the course is well structured with good correspondence between course elements, objectives and relevancy. However, the questions regarding the adequacy of the course material truly divides the students. Many feel that they were to ill-prepared for the different tasks they were facing and would like to consult a text book or lab manual. Since we are experimenting with the minimally guided approach we would anticipate that some students would feel that the course material is insufficient since the idea is that they themselves should address the original literature or turn to the pharmacopoeias or similar regulatory guidelines. It is obvious that the background knowledge of the subject is too limited for them to know where to turn for relevant literature. We must, therefore, find a way to get students on the right track from the beginning so that they do not feel that they are wasting precious time chasing answers where none can be found.

Questions 7 and 8 are interpreted as a general approval of the course content and relevancy. We also consider this a validation of the problem based approach that we have tried to implement. It seems like the academic level has been appropriate as well as the workload. However, it seems that a better distribution of the load before and after the Christmas break should be implemented. The time spent on the course is slightly at the low end suggesting that we could increase our expectations of student preparation and perhaps introduce some immunology literature as “self study” or as preparation for the individual experiments. This would also in part be a response to the students who state that they would like more theory and like to spend the lab pauses more efficiently. Another obvious request from the student is to increase communication. I believe that this in part relates to the inexperience from us as teachers in using the minimally guided approach. In our eagerness to make the students work independently and without too many inputs from our side, we may have overlooked the need for communication in respect to other aspects such as; general information, technical questions and curriculum or exam information. A more structured approach to the communication is therefore desired.

Conclusion

All in all, we conclude that the students, in general, liked the new format and explicitly (in the evaluation form) showed their appreciation of the new core aspect that we have build the new course around, namely:

- The QC report
- That we centred the course around tests with an industrial applicability
- That the same products were tested repeatedly by various tests as one project and
- The lectures by QC professionals.

Moreover, the majority of students recognized the PBL approach to the course and appreciated that they had ample time to test and re-test the same products during the course. Most importantly, the students appreciate the oral presentations and subsequent debate regarding results and result evaluation and actually suggested that this should include opponent group evaluation of the QC report.

We also feel that we have met the majority of our success criteria in that: The overall design of the course allowed industrial and research based experiments to be conducted along with theoretical considerations, self-reflection and independent study.

The students felt that they had a problem-based approach to the questions raised in the course material, but it seems that they did not find that the guidance is adequate.

The students displayed in-depth topic understanding, read and understood the scientific literature presented, and in part displayed a critical approach to own results. Students have also suggested relevant improvements.

For the teaching group, there was a general consensus that the new format supersedes the old and that we all like the problem-based approach using analysis of two pharmaceuticals in multiple test systems. Also, the inclusion of QC professionals seems to inspire the students and we as teachers appreciate the validity it gives our topic choice. We also felt that the students learned from their mistakes and it seems that the final QC report with the "go/no-go" decision regarding the release of pharmaceuticals encouraged the students to profoundly reflect on their obtained results.

We feel that student acceptance of and consent to the format chosen was very limited and that they were frustrated over the minimally guided approach. In some cases, they felt distanced from the teachers even though teachers were heavily represented in the laboratory and in the classroom

sessions. I do not think that this shows a discontent with the format, in general, but that it reflects a frustration among students who simply do not know what is expected of them. In my opinion, this is a clear example of a misinterpreted (or lack of) didactical contract between students and teachers. We should from day one have informed the students how we expected that the minimally guided approach should be used in the lab, how our teacher involvement should be in the student projects and finally, how this approach affects the exam. Moreover, it should be underlined that our lack of "teaching" should be compensated in part by an independent literature search by the students (at any given opportunity) and a subsequent discussion of the data collected.

If the increased focus on the didactical contract will make more students accept the format of our project based, minimally guided approach remains to be seen. But it is the intention of the teaching group to keep the herein described course format. The changes suggested by the students will be implemented to further improve the student acceptance and, hopefully thereby, the willingness and ability to learn.

All contributions to this volume can be found at:

http://www.ind.ku.dk/publikationer/up_projekter/2010-3-1/

The bibliography can be found at:

http://www.ind.ku.dk/publikationer/up_projekter/kapitler/2010_vol3_bibliography.pdf/