

Use of a multimedia tool for undergraduate industrial pharmaceutical training

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Abstract: The article studies whether training prior to laboratory work (with a multimedia interactive programme), as a complement to the traditional practical-theoretical teaching of tablet manufacturing, has brought advantages to pharmaceutical technology learning and, in consequence, increased the quality of the tablets produced by the students in the educational pilot plant.

Evaluation is a key aspect in the learning process outlined in this paper.

Computer-based learning shows that prior training is useful as a primary or supplementary instruction tool for teaching pharmaceutical technology skills in the pharmaceutical pilot plant. This previous training affected certain factors positively, such as: general knowledge of tableting and GMP rules, fewer incidents reported in the pilot plant, less equipment breakdown and better compliance with Good Manufacturing Practices. However, it did not affect some parameters of the quality of the tablets manufactured (hardness, % output and mean weight), and it enhanced substantially their dissolution quality.

Keywords: Evaluation methodologies, improving classroom teaching, media in education, teaching/learning strategies, simulations, multimedia, pharmaceutical technology.

Abbreviations

API: Active Pharmaceutical Ingredient

GMP: European Union Good Manufacturing Practices

SOP: Standard Operational Procedure

CD-ROM: Compact Disc – Read Only Memory

SD: Standard Deviation

RSD: Relative Standard Deviation

USP: United States Pharmacopeia

Introduction

In the Bologna Declaration (1999), the European Ministers of Education undertook to establish the European Higher Education Area by 2010. The Bologna Declaration encourages, among other things, European co-operation in

ensuring quality in higher education, with a view to developing comparable criteria and methods (ENQA, 2007). As a method, multimedia software in computers is one of the most popular technological advances in recent years, and many programs have been developed to improve skills and student accomplishment in a wide array of pharmacy or medicine subjects (Rappa *et al.*, 2006; Brenton *et al.*, 2007; Holzinger *et al.*, 2009). After identifying opportunities to correct deficiencies in students' pilot-plant work, computer-delivered training was considered an option for improving students' performance. In addition, many new training materials (CD-ROMs, videos, web sites, internet chat rooms etc.) for pharmacy have been used to give pharmacy courses (Schlicht *et al.*, 1997; Shrewsbury, 2000; Roffman *et al.*, 2002; Chaikoolvatana and Goodyer, 2003; Sibbald, 2003; Tran *et al.*, 2003; Alsharif *et al.*, 2005; Vanderbush *et al.*, 2005; Brandys *et al.*, 2006; Kidd and Stamatakis, 2006; Sancho *et al.*, 2006; Persky, 2007; Strong, 2007; Green and Levi, 2008; Hasan, 2008). There are many teaching materials available in pharmacy, but several areas such as pharmaceutical technology or operational procedures (Davidow and Emerson, 2001; Tapia *et al.*, 2002; Nivet, 2005; Tapia *et al.*, 2005; Tapia *et al.*, 2009) are less developed than others (clinical or medicine). Professional materials are also available and can be used in training: see the extended catalogue on the webs of Micron video (n.d), Association of Health System Pharmacists (n.d.), Parenteral Drug Association (n.d) or Publicacions de la Universitat de Barcelona (n.d.). Most of these materials are videotapes that have been converted to DVD format.

Nevertheless, other computer programs known as expert systems are available to help in the formulation of capsules (on the web of Capsugel, n.d.), or tablets (Pérez *et al.*, 2006; Suñé *et al.*, 2008) or the development of HPLC methods (Mulholland *et al.*, 1991) and the design of in-process controls (Doherty *et al.*, 2003). These are just a few examples: more can be found in the reviews by Rowe, 2006 and Thakkar, 2007.

Within the framework of University Educational Innovation at the University of Barcelona, the Pharmaceutical Technology group received economic assistance to work out a multimedia interactive application for Pharmaceutical Technology. Developed over time, it was validated in the computing laboratory with groups of undergraduate Pharmacy students and professionals from the pharmaceutical industry. These studies helped improve the application steadily and continuously, detecting weak points before its completion, which was optimal for its development and final quality, arguing that the use of these technologies improves the quality and ability of the students who took such training, as other authors have remarked (Barnett and Matthews, 1997; Shrewsbury, 2000; Barnett *et al.*, 2003; Hunter *et al.*, 2003; Berner and Adams, 2004; De Muth, 2006; Limniou *et al.*, 2009). Further, positive experiences have been reported with our multimedia learning, as a broader range of knowledge and virtual experience became available.

Traditionally, teaching methodology in our university consists of a traditional lecture format (12h), seminar sessions devoted to solving problems and calculations (6h) and laboratory experiments (6h). The incorporation of multimedia materials is used to explain the tableting process in a GMP environment as it is normally performed in the pharmaceutical industry but in this case adapted to our university pilot plant, which is obviously difficult to teach in a lecture style format.

In addition, the interactive interface facilitates the understanding of details and the basis of each step in the process. This application was planned to enhance the aptitude of students for practical work and to solve common problems detected in previous courses during tablet manufacture, relating to the quality of the products manufactured, such as non-compliance with specifications, incidences, equipment breakdown and cross-contamination due to poor hygiene. It was expected that the use of a CD-ROM (two additional hours) would improve both academic performance and the quality of the products manufactured, i.e. tablets, so that an exhaustive monitoring was carried out on batches manufactured throughout two academic years: 67 for the first year and 56 for the second one.

Material and methods

Description of the multimedia material developed

The application consists of several chapters in Spanish. The planned learning strategy is different for each of the four sections. The objective was to develop an educational interactive CD-ROM. The software is full-colour illustrated and contains graphics, diagrams, tables, animations and videos, some of them obtained directly from the SDM (Service of Development of Medicines), while others were designed by the authors. The SDM is a GMP-compliant pharmaceutical technology pilot plant in the Faculty of Pharmacy. Each feature was geared to the item involved in the learning process. The parts of the application involved in learning the wet granulation technique to produce the tablets are the third and fourth. The initial screen of the program is shown in figure 1. All four parts include an evaluation system to assess whether the pre-established minimal knowledge level was achieved, which feeds into the final report on the student, which has to be printed by him/her and given to the teacher before the student is allowed to enter and work in the pilot plant (because initial GMP training is a requirement at a pharmaceutical centre).



Figure 1. Main screen of the multimedia application, with commands to enter the four parts of the program: Part I. Visit to the Service of Development of Medicines (*Visita virtual al SDM*). Part II. Good Manufacturing Practice (*Normas de Correcta Fabricación*). Part III. Practical Training (*Entrenamiento*). Part IV. Practicals (*Prácticas*). At the bottom of the screen, three more commands: MAPA: map program, SALIR: exit, INFORME: report with the results (you have to enter the student code beforehand).

The following parts make up the multimedia interactive application:

Part I. Virtual visit to the Service of Development of Medicines (SDM): It is a graphic representation of the installations (lay-out, diagrams, flow sheets) of the pilot plant and examples of technical documentation as SOPs (Standard Operation Procedures). See figure 2.

Part II. Good Manufacturing Practices (GMP): Tutorial and hypertext with graphic images that summarize Good Manufacturing Practices. Investigation of extreme cases through pictures, press reports etc. See figure 3.

Part III. Training: Interactive tutorial in which the operating and behaviour proceedings are highlighted due to the interaction of the students with all and every one of the steps of the manufacturing process, for example, how to fill virtual equipment labels, precautions to take etc. See figure 4.

Part IV. Practice: Resolution of real manufacturing problems. In this part, batch documentation is reviewed as if a real case.



Figure 2. First part of the application's screen: Virtual visit to the Service of Development of Medicines. *Part I. Virtual visit to the Service of Development of Medicines (SDM).* The photo shows the Liquids area (Área de líquidos). The diagram on the right describes the different rooms in this area; from up to down and left to right: Galenic control (Control galénico), Stability room (Sala de estabilidad), Semi-solids (Semisólidos), SAS of Steril zone (SAS de Zona estéril), Aerosols (aerosols), Liophilizator (Liofilizador), Liquids (Líquidos), Steril zone (Zona estéril), Liquids wash (Limpieza líquidos), Steril zone wash (Limpieza zona estéril), Dressing room (Vestuario) and Solids area (Área de sólidos).

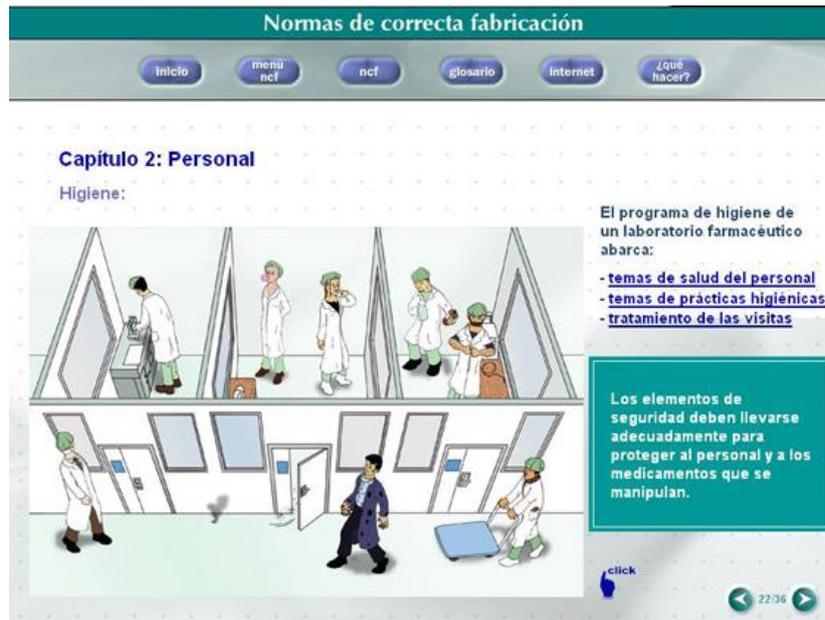


Figure 3. Part II. Good Manufacturing Practices (GMP). Second part of the application: Good Manufacturing Practices. Example of presentation of chapter 2 of GMP: Personnel. The student must click on the non-compliant items that may appear on the image. When clicking, an explanatory window pops up.



Figure 4. Part III. Training. Third part of the application: Training for tablet manufacturing. Example of a screenshot showing the label to be used in the laboratory after cleaning the sieving machine.

The application took two hours to be completed by the students, and it took place in a computer's classroom of the Faculty of Pharmacy in groups of 16 students.

Participants

They consisted on fourth year students from two academic years, all of them with a similar knowledge background. All of them had previously attended classes on the compulsory subject Pharmaceutical Technology I (seven credits ECTS), during the first semester of the academic year.

Instructions and method of analysis

The results, in terms of three quality parameters from the tablets obtained in the pilot plant by students, are evaluated. The working hypothesis is that the quality of the tablets manufactured during the academic year 2007/2008 should be tangibly better than the ones manufactured during the academic year 2006/2007. Tablets from 2007/2008 were manufactured by students of the subject 'Pharmaceutical Technology II' after virtual training. Data from 2006/2007 were for students who did not make prior multimedia virtual visit training. However, it can be taken into consideration that the background of the two groups was similar.

To analyse the study, data indicative of quality, available from the batches manufactured during both these academic years, were collected.

Among other quality parameters, the following were selected:

Batch output: a high output means that the operator has taken into account the procedure instructions and has worked accurately.

Mean hardness of five tablets (obtained during manufacture, every 5 minutes up to the end of the batch). Hardness within the limits indicates that the previous formula has been drawn up properly, and the steps of the process (granulation & mixing & tableting) and operating specifications have been respected.

Mean weight of five tablets (obtained during manufacture every 5 minutes up to the end of the batch). Homogeneous weight means within the specifications show very clearly that the previous formula was drawn up according to the specifications, respecting all the steps.

Percentage of API dissolution

The USP dissolution test was performed on a sample of manufactured batches. The hypothesis is that if students improved their performance in manufacturing, product uniformity would also improve, and this fact is reflected in the percentage of dissolution obtained.

For the analysis of the parameters mentioned above, results of 67 batches from the academic year 2006/2007 and 56 from the academic year 2007/2008 were collected, except for the testing of percentage of API dissolution. In this last case, the number of batches analyzed differs due to differences in the members' number in each practice group. So in 2006/2007 academic year were tested 57 batches, and 30 in the year 2007/2008. All of them were tabulated and rationalised (anomalous results, uniformity of measure units, incidents). Both groups of data were subjected to a Student's t-test to show whether there was a significant statistical difference between them.

Then, after finishing their practical work, students were evaluated by the teacher in a written examination. The questionnaire had 20 questions about the

tablet manufacturing technique and general GMP rules. Answers from the two academic groups were compared.

Results

Quality inputs from the batches are shown in table 1, along with the Student's t-test statistical summary for the three parameters of the process tested. Table 2 shows dissolution percentages of the batches tested.

Results from the In-Process Control: batch output

Table 1 shows the basic statistics of the data, in which it can be seen that the output obtained is slightly higher for batches manufactured by the group that had done the multimedia application previously and that its results show less variability (5.4% against 7.9%). Another point to be stressed is that 49 of the 67 batches (73.2%) manufactured after prior training with the multimedia application can be considered correct (output \geq 85%), whereas in the previous year only 31 of the 56 of the batches (55.2%) were correct. Likewise, we can deduce that multimedia training improved the regularity, homogeneity and reproducibility of the batch's manufacture, since the variation obtained is 31% less in 2007/08 (RSD=5.74) than in 2006/07 (RSD=7.95), which clearly shows less dispersion and, in consequence, more regular manufacture.

However, the t-test will show whether such differences are significant. As Table 1 shows, the factor 'academic year' (with previous multimedia or not) does not affect results negatively, and it is reasonable to attribute the variability found to experimental error.

	Without multimedia 2006/07	With multimedia 2007/08	Without multimedia 2006/07	With multimedia 2007/08	Without multimedia 2006/07	With multimedia 2007/08
RESULTS	Batch output (%)		Hardness (N)		Mean weight (mg)	
MEAN	84.6	86.0	79.0	80.5	351.6	350.9
MAXIMUM	94.8	97.8	114.0	116.5	368.46	374.4
MINIMUM	55.7	61.0	44.8	57.6	324.0	332.8
n	67	56	67	56	65	55
SD	6.72	4.7	12.14	12.10	7.36	8.96
RSD	7.95	5.47	15.37	15.03	2.09	2.55
t-test	1.81389		0.475253		0.245519	
p-value	0.18055		0.49189		0.62116	
alpha	3.91946		3.91946		3.92148	

Table1. Quality inputs and statistical indicators from the batches

Results from the In-Process Control: Mean Hardness of five tablets

Tablet testing for hardness involves the measurement of five tablets every 5 minutes, with hardness checked by means of a tablet hardness tester. Moreover, the mean of the results obtained for the five tablets is calculated. In this chapter, mean hardness from each batch (manufactured in each academic year) is compared, taking as a variable the fact of having previously studied the process with the multimedia programme (2007/2008) or not (2006/2007). In this case, basic statistics and the analysis of variance from data were also carried out.

In reference to the parameter 'hardness', there is a slight difference in favour of the batches manufactured after previous multimedia programme training, with very similar variation coefficients. The t-test shows whether these differences are significant. Table 1 shows that the factor 'academic year' (previous multimedia training or not) does not negatively affect the differences of the results, so that the variability found can reasonably be attributed to experimental error.

Results from the In-Process Control: Mean Weight of five tablets

Weight testing involves measuring five tablets every 5 minutes and checking tablet weight on a precision balance. The mean of the results obtained is also calculated. In this chapter, mean tablet weight from each batch (manufactured in each academic year) is compared, taking as a variable the fact of having previously studied the process with the multimedia programme (academic year 2007/08) or not (academic year 2006/07). In this case, basic statistical tests and the analysis of variance (Table 1) of data were also carried out.

For the parameter 'weight', there is a slight difference in favour of the batches manufactured without previous training, showing a lower variation coefficient than the other group. The t-test reveals whether these differences are significant. Table 1 shows that the factor 'academic year' (previous multimedia training or not) does not negatively affect the differences in the results for weight, so that the variability found can be reasonably attributed to experimental error.

Results from quality control laboratory: Percentage of API dissolution

In reference to tests performed on batches of tablets, table 2 shows the results obtained of the dissolution percentage for tablets of paracetamol. The batches manufactured in 2006/2007 prior to multimedia training show a mean of 85.6% dissolution, a result that improved up to 93.7 % in 2007/2008, with multimedia training. Furthermore, the improvement is reflected in less variability, since the range of percentage of dissolution has narrowed. Also, standard deviation (SD) and relative standard deviation (RSD) were reduced. Only one batch out of 29 does not meet USP specifications for dissolution percentages, whereas before the non-compliance occurred in 19 batches out of 57.

	Without multimedia 2006/07	With multimedia 2007/08
RESULTS	Dissolution (%)	
MEAN	85.6	93.7
% MAX	114.2	102.2
% MIN	50.6	83.9
NUMBER OF BATCHES TESTED	57	30
SD	16.9	4.37
RSD	19.8	4.66
VALUES ≥85%	32	29
VALUES ≤85%	19	1

Table 2. Results from dissolution percentages

Results of the practices test

Results are shown in table 3. Most of the tests were collected by the teachers because it was compulsory to deliver them before leaving the pilot plant. This makes 254 tests (95%) for the first year and 216 (94%) for the second year.

No significant differences appear for the two sets of tests examined. The scores were high enough in both cases. Only 1.39% of students did not reach the objective (3 students) when multimedia training was given previous to lab work, and 7.87% (20 students) did not reach the "pass mark" (7 over a maximum of 10) when tablet training was taken without previous multimedia learning. The authors suggest that the material helps students to retain the information better.

RESULTS	Without multimedia 2006/07		With multimedia 2007/08	
	Practice test			
NUMBER OF PARTICIPANTS:	254		216	
MEAN QUALIFICATION (OVER 10):	8.4		8.9	
GRADE QUALIFICATIONS:	<i>n</i>	%	<i>n</i>	%
>9-10	90	35.43	103	47.69
>8-9	72	28.35	56	25.93
>7-8	42	16.54	30	13.89
>6-7	30	11.80	24	11.11
<6	20	7.87	3	1.39
TOTAL	254	100	216	100

Table 3. Results from the practice tests

Discussion and conclusion

The results from the final test showed that students' understanding of the tablet manufacturing process was enhanced by use of the CD-ROM. The results suggest that CD-ROM instruction to support conventional lectures is a more effective teaching technique than just conventional lectures and laboratory practice. Despite the foreseen expectations, results show that the quality of batches (analysed according to the operating parameters of output, hardness and weight) did not improve significantly as a consequence of previous multimedia training (2 hours), but this result is usual in this kind of research (Aly, 2005; Anun, 2003; Chaikoolvatana and Goodyer, 2003; Roffman *et al.*, 2002; Shrewsbury, 2000). However, an improvement relating to percentage of dissolution and incidents throughout the manufacturing process (a reduction of them) was found. The organisation of the practices and compliance with Good Manufacturing Practice were also substantially better, because the students knew beforehand what they were going to do and the importance of basic processes such as cleaning, making them better prepared to complete laboratory exercises and feel more confident of their own skills in the pilot plant. In fact, many published studies share this positive perception about the effects of the use of multimedia software in training (Hasan, 2008; Vanderbush *et al.*, 2005).

It is noted that the dissolution results have improved significantly in 2007/2008 batches, because in fact most of the batches tested (29 out of 30) meet the dissolution specification (> or = 85 %), opposite to 2006/2007 results which 35% of batches were outside dissolution specifications. Also, 2007/2008

batches show a lower variability (RSD inter-batch = 4.66 %). It can be assumed that the changes incorporated (multimedia training previous to manufacturing) in this group have improved the quality of the tablets as for their dissolution profile. Finally, in our view, the acquisition of practical skills is reinforced by the use of a media application prior to practice courses, which helps explain GMP and tableting concepts, because the information is enhanced by animation and movements that improve visual acquisition of concepts (e.g. labelling equipment with a green label after cleaning), which can then be followed in laboratory work. It invariably proves cost-effective, especially when time is limited and equipment is in short supply. There are several factors which make multimedia computer simulations ideal for use in pharmacy education, especially now, when a new vision of teaching is needed for a common worldwide university.

Further studies are needed to identify the factors in this kind of programme that might affect performance. It is necessary to choose the right indicators, which can prove the effectiveness of this teaching material. Currently this training could be undertaken by the students at distance (i.e. without teacher supervision), which would reduce the burden of teaching repetitive tasks, so allowing free time to spend on other teaching duties. In future, it is intended to study whether the presence of the teacher affects students' performance.

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