Approaches to Education of Pharmaceutical Biotechnology in Faculties of pharmacy

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Abstract: Pharmaceutical biotechnology is developing rapidly both in academic institutions and in the biopharmaceutical industry. For this reason, FIP Special Interest Group of Pharmaceutical Biotechnology decided to develop a questionnaire concerning pharmaceutical biotechnology education. After preliminary studies were completed, questionnaires were sent to the leading scientists in academia and research directors or senior managers of various Pharmaceutical Biotechnology Companies in order to gather their views about how to create a satisfactory program. The objectives of this study were as follows:

- To review all of the graduate and undergraduate courses which are presently available worldwide on pharmaceutical biotechnology in Faculties of Pharmacy.

- To review all of the text books, references and scientific sources available worldwide in the area of pharmaceutical biotechnology.

When replying to the questionnaires, the respondents were asked to consider the present status of pharmaceutical biotechnology education in academia and future learning needs in collaboration with the biotechnology industry. The data from various pharmacy faculties and biotechnology industry representatives from Asia, Europe and America were evaluated and the outcome of the survey showed that educational efforts in training qualified staff in the rapidly growing field of pharmaceutical biotechnology is promising. Part of the results of this questionnaire study have already been presented at the 57th International Congress of FIP Vancouver, Canada in 1997.

INTRODUCTION

Pharmaceutical biotechnology which is an interdisciplinary, specific and innovative field of pharmaceutics is developing rapidly both in academic institutions and in the pharmaceutical industry. In the Pharmacy field, biotechnology has been used to develop novel diagnostics and therapeutics for healthcare. The increasing importance of this technology in healthcare is affecting almost every aspect of pharmacy practice. Pharmaceutical biotechnology has concentrated primarily on recombinant DNA technology, monoclonal antibodies, vaccines and gene therapy. Hundreds of employees now work at more than 1000 biotechnology companies in the USA and academic scientists, personnel of the government laboratories and biotechnology centers are not included in this number. Academic research has focused on biotechnology derived drug products and companies, which dealt with traditional drugs in the past, have now become more involved in biopharmaceuticals. New working associations have also been established between industry and universities. Basic and applied research in pharmaceutical biotechnology generates knowledge that is applied to the needs of the society. A number of pharmaceutical...
biotechnology books have been written. Moreover, graduate / undergraduate courses and programs have been initiated in some Pharmacy Faculties around the world [1-5].

Taking into consideration this rapid development, FIP Special Interest Group of Pharmaceutical Biotechnology decided to develop a questionnaire concerning pharmaceutical biotechnology education in order to determine its present status and future needs [6]. The objectives of this worldwide questionnaire study were to review all of the undergraduate courses and textbook references / scientific sources which are presently available in the area of pharmaceutical biotechnology. One of the major aim was to determine the borders and milestones of pharmaceutical biotechnology in pharmacy education from both a qualitative and quantitative aspect.

The prepared questionnaires were distributed to leading scientists in academia and research directors or senior managers of Pharmaceutical Biotechnology companies to gather their opinions about how to create a satisfactory educational program in this field. The proposed undergraduate teaching program in pharmaceutical biotechnology mainly involved nine topics. The questionnaire consisted of 10 questions regarding the teaching of pharmaceutical biotechnology in undergraduate programs in academic institutions (Appendix I). The questionnaires were sent to 110 faculties/firms in 18 countries in Asia, Europe and America and a total 52 replies were received (Table Ia and Ib).

The data was evaluated and the outcome of the questionnaires showed that educational efforts in training qualified staff in the rapidly growing field of pharmaceutical biotechnology is quite promising.

**METHODS**

After completing the preliminary studies for the formatting of the questionnaires, drafts were sent for review and feedback to leading scientists who were pioneers of this area to seek their views. After revision the questionnaires were distributed. Worldwide in collaboration with FIP and AAPS Biotechnology Section and related groups in Europe.

In 1996 another collaborative survey with the European Association of Faculties of Pharmacy (EAFP) was completed successfully by our department on "Developing Teaching Objectives in Pharmaceutical Technology”. Since pharmaceutical technology is a well-established program that is included in the curriculum of almost all pharmacy schools around the world but since this was an EAFP survey, the questionnaire only covered the Pharmacy schools in Europe. However, when preparing this present survey on pharmaceutical biotechnology we had to undertake a global survey as this is a new program which is in the establishment phase in most academic institutions.

We distributed this questionnaire on "Current Status and Future Needs of Pharmaceutical Biotechnology Education" to 110 institutions (academic & companies). Distribution of the questionnaires was in two parts. In the first phase a total of 56 questionnaires were distributed while 21 replies were received. In the second part of the survey, a total of 54 questionnaires were distributed and 31 replies were returned. In total 110 questionnaires were distributed and 52 responses were evaluated. Tables Ia and Ib show the distribution of the survey. Questionnaires were sent to 13 countries in Europe, 2 countries in America and 3 countries in Asia. 27 replies were received from Europe; 5 being from industry, 22 from academic institutions. From America, 11 from academic institutions, 7 from industry. Finally from Asia 7 replies were received, all from academic institutions. We evaluated 52 replies and estimated the reasons for failing to set all to replies to be:

- It is practically current impossible to get 100 % response for such a survey.
- In most of the pharmacy schools to which the questionnaire was sent, there were no pharmaceutical biotechnology courses in their pharmacy curriculum.
Table 1 (a and b). The Suggestions of the Year-Semester Distributions of Pharmaceutical Biotechnology Courses in Pharmacy Curriculum

<table>
<thead>
<tr>
<th>Year</th>
<th>Semester</th>
<th>Yes (hrs / week)</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>II</td>
<td>III</td>
<td>IV</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**AMERICA**

- **Canada**
  - MRCC: 2
  - PCA: 1
  - Bio: x
  - BDSI: x

- **U.S.A.**
  - ACA: 1
  - AU: 3
  - BDSI: x
  - DAVA (-): x
  - GenMed (-): x
  - HWS: 2
  - NWU (-): x
  - RW Johnson (-): x
  - Scios: 4
  - USC (-): x
  - UCSF: 2
  - UIC: 2
  - KU: 3
  - UK: x
  - UM: x
  - UW: 3

**ASIA**

- **Israel**
  - HeU: x

- **Japan**
  - KyoU: 3
  - HaU: x
  - HoU: x
  - KuU: 2
  - UT: 4

- **Republic of China**
  - TMC: 4

(-): Repliers stating [hat (hey have no idea; 0: Optional; C: Compulsory)

**AMERICA**


**ASIA**

Israel: Hebrew University*(HeU); Japan: Kyoto University*(KyoU). Hokkaido University* HaU). Hoshi University* (HoU), Kumamoto University* (KuU), University of Tokyo* (UT); Republic of China: Taipei Medical College (TMC)

*College. Department and/or Faculties of Pharmacy

*Duration of courses was not stated
### Table 1b.

<table>
<thead>
<tr>
<th>Year</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>V</th>
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<th>III</th>
<th>IV</th>
<th>V</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semester</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

**EUROPE**

**CZECH REPUBLIC**
- VFU: 6
- UKP: 5

**Finland**
- UKu: 2 2

**France**
- ENSAIA-INPL: x x 10-15
- UN: x x 5-10
- UP-Stud: 4 4 5-10
- ULP: 5 5 10

**Germany**
- GU: 4 10
- UB: x x 5

**Hungary**
- SUM: 3 1

**Italy**
- UUr: x x 3-5
- UP: 2 2 5
- UDSDP: 3 5

**Slovenia**
- ULj: 3 4-5
- KRKA: 4 10

**Spain**
- USdeC: x x 5-10
- UCdeM: 7 20

**Sweden**
- Astra: x x 5
- UUp: 4 20

**Switzerland**
- UG: x
- ETHZ: x x 15

**The Netherlands**
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(Tables 1b). Contd .......

<table>
<thead>
<tr>
<th>Yes (hrs / week)</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semester</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>O</td>
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<tr>
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<td>I</td>
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<td>II</td>
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<td>III</td>
</tr>
<tr>
<td>IV</td>
<td>IV</td>
</tr>
<tr>
<td>V</td>
<td>V</td>
</tr>
</tbody>
</table>

- (-): Repliers stating that they have no idea; O: Optional; C: Compulsory

EUROPE


*College. Department and/or Faculties of Pharmacy

1Duration of courses was not stated

It was our approach to send the questionnaires to some of the academic institutions even though we already knew that they did not have biotechnology courses in their pharmacy curriculum to obtain their opinion about this new and rapidly developing field of pharmaceutical sciences and to learn whether they had plans for designing such a program.

Pharmaceutical biotechnology related companies were targeted because we had a strong belief that (see the related question in the questionnaire) industry-academia collaboration is required in this area. After completing the survey, incoming data was evaluated and tabulated for presentation and discussion.

RESULTS & DISCUSSION

Regarding the question about including pharmaceutical biotechnology courses in Pharmacy teaching programs of Pharmacy faculties, all of the respondents from faculties and companies (America, Asia and Europe) were in agreement about the inclusion of pharmaceutical biotechnology courses in undergraduate teaching programs of pharmacy faculties. Here it is important to note that all of the academic institutions and related companies were well aware of the significance and status of this novel and advancing field in pharmacy teaching programs.

In a previous survey, EUFEPS Committee on Industrial Relations (CIR) was asked by the Executive Committee to search for the problems faced when recruiting qualified personnel at the post doctorate levels in the pharmaceutical industry [7]. As a result of this survey it was concluded that there was a great shortage of qualified candidates at Ph.D. level in the pharmaceutical biotechnology area. In fact, Ph.D. programs of pharmaceutical biotechnology in pharmacy schools are in their infancy and in the near future qualified Ph.D. personnel will be needed to fulfill the demand.
APPENDIX I

PREPARED QUESTIONNAIRE CONSISTED OF 10 QUESTIONS REGARDING PHARMACEUTICAL BIOTECHNOLOGY TEACHING IN UNDERGRADUATE PROGRAM IN ACADEMIC INSTITUTIONS

1- What is your opinion about pharmaceutical biotechnology courses in pharmacy teaching programs of pharmacy faculties ?

2- Do you have pharmaceutical biotechnology courses in your pharmacy curriculum ?

3- In which semester and grade do you think pharmaceutical biotechnology courses should be initiated ?

4- Which courses do you think should be essential before taking the pharmaceutical biotechnology course ?

5- What should be the percentage of pharmaceutical biotechnology courses in total pharmacy education ?

6- In the proposed program you will find the suggested topics (in detail) for undergraduate teaching program of pharmaceutical biotechnology. Please indicate your opinion and evaluate the topics up to the criteria shown below.

7- There should be additional topics.
   If your answer is yes please list the topics and evaluate according to the criteria shown above.

8- Some topics should be excluded from the list in the proposed program.
   If your answer is yes please mark it on the concerning column and cross out these topics on the list given in detail in the proposed program.

9- Do you think there should be an academia and industry collaboration in pharmaceutical biotechnology teaching program ?

10- Academia / Industry relationship ratio 50 : 50
    25: 75
    75: 25

Most of the responding faculties of Europe and Japan stated that there were pharmaceutical biotechnology courses in their pharmacy curriculum. Respondents from the USA pointed out that pharmaceutical biotechnology courses should be included as 2-3 hrs/week in undergraduate programs as a mandatory course. Regarding the initiation time of those courses, responses from the USA suggested mainly the 2nd and 3rd years.

Replies from Asia appeared to be more variable since some of the respondents' suggestions indicated that courses should be optional in undergraduate programs. Most of the respondents suggested a 2-4 hrs/week for the duration of courses while the generally suggested initiation time was the 3rd year of the pharmacy undergraduate program.

Evaluation of the responses from Europe showed that suggestions for the duration of courses was variable from 1-7 hrs/week, while the initiation time of courses was proposed to be the 3rd and 4th years. However, almost 50 % of the respondents suggested that these should be optional. Differences in the approaches of the universities and related companies in America, Asia, Europe might be due to the variance in the duration of the pharmacy education in these countries. For thorough examination of the replies regarding the year-semester distributions of
Table 2. Suggested Essential Topics Before Taking Pharmaceutical Biotechnology Course

<table>
<thead>
<tr>
<th>Suggested Topics</th>
<th>University / Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Biochemistry</td>
<td>Scios</td>
</tr>
<tr>
<td>Medical Biochemistry</td>
<td>KU</td>
</tr>
<tr>
<td>Enzymology</td>
<td>HMS</td>
</tr>
<tr>
<td>Microbial Biochemistry</td>
<td>US</td>
</tr>
<tr>
<td><strong>Biology</strong></td>
<td>UIC/UKu/VFU/SUM/UP/TMC/KRKA/UDSDP</td>
</tr>
<tr>
<td>Cell Biology</td>
<td>UU/KyoU/Bio/BS/ETHZ/UUp/ACA</td>
</tr>
<tr>
<td>Molecular Biology</td>
<td>UU/NWU/HMS/UP-Sud/U/KLyO/U/UUr/HeU/ULj/MRCC/ETHZ/UUp</td>
</tr>
<tr>
<td><strong>Chemistry</strong></td>
<td>RW Johnson/KyoU/UB/Astra/Uk/VFU/TMC</td>
</tr>
<tr>
<td>Chemical Engineering</td>
<td>MRCC</td>
</tr>
<tr>
<td>Basic Organic Chemistry</td>
<td>UU</td>
</tr>
<tr>
<td>Organic Chemistry</td>
<td>UK/UW/Bio/UKP/UP/TMC/ETHZ/UUp</td>
</tr>
<tr>
<td>Medicinal Chemistry</td>
<td>RW Johnson/VFU/MC/KRKA</td>
</tr>
<tr>
<td>Polymer Chemistry</td>
<td>HMS/UP-Sud/HAU</td>
</tr>
<tr>
<td>Physical Chemistry</td>
<td>Bio/UUp/HAU</td>
</tr>
<tr>
<td>Analytical Chemistry</td>
<td>Bio/UKPh/MC/ACA</td>
</tr>
<tr>
<td>Pharmaceutical Chemistry</td>
<td>UU/UG/SGM/UG/UDSDP</td>
</tr>
<tr>
<td>Instrumental Analysis</td>
<td>Bio/ULP</td>
</tr>
<tr>
<td><strong>Mathematics</strong></td>
<td>UIC</td>
</tr>
<tr>
<td>Calculus</td>
<td>Bio</td>
</tr>
<tr>
<td>Differential Equations</td>
<td>Scios</td>
</tr>
<tr>
<td><strong>Statistics</strong></td>
<td>UIC</td>
</tr>
<tr>
<td>Biostatistics</td>
<td>Bio</td>
</tr>
<tr>
<td><strong>Basic Pharmaceutics</strong></td>
<td>UICWW Johnson/UL/Scios/USdeC-TMC</td>
</tr>
<tr>
<td>Biopharmacy (Pharm. Technol)</td>
<td>UU/Astra/SUMAJ/USdeC</td>
</tr>
<tr>
<td>Physical Pharmacy</td>
<td>UK</td>
</tr>
<tr>
<td>Suggested Topics</td>
<td>University / Company</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Dosage Form Design</td>
<td>UK</td>
</tr>
<tr>
<td>Drug Delivery Systems</td>
<td>UL</td>
</tr>
<tr>
<td>Formulation: Basic knowledge</td>
<td>UsdeC</td>
</tr>
<tr>
<td>Pharmaceutical Analysis</td>
<td>RW Johnson</td>
</tr>
<tr>
<td>Pharmaceutical Technology</td>
<td>UDSDP/UN</td>
</tr>
<tr>
<td>General Biotechnology</td>
<td>HMS</td>
</tr>
<tr>
<td>Vaccines</td>
<td>UL/ULP</td>
</tr>
<tr>
<td>Proteins</td>
<td>UP-Sud/ULP/HaU</td>
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<tr>
<td>Genomics+Nucleic Acids</td>
<td>UP-Sud</td>
</tr>
<tr>
<td>Molecular Genetics</td>
<td>NWU/ULj/UsdeC</td>
</tr>
<tr>
<td>Monoclonal Antibodies</td>
<td>UL</td>
</tr>
<tr>
<td>Recombinant Technology</td>
<td>UL</td>
</tr>
<tr>
<td>Fermentation + Cell Culture</td>
<td>ULP</td>
</tr>
<tr>
<td>Microbiology</td>
<td>UU/AU/UM/HMS/UB/UKP/HeU/VFU/ULj/SUM/UP/TMC/KRKA/UDSDP/ENSAIA-INPL</td>
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<td>Immunology</td>
<td>KU/AU/UP-Sud/UKP/I-leU/VFU/ULj/SUM/UP/USdeCTMC</td>
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<tr>
<td>Pharmacology I+II</td>
<td>KU/Ku/VFU/TMC/ACA</td>
</tr>
<tr>
<td>Molecular Pharmacology</td>
<td>Uur</td>
</tr>
<tr>
<td>Pharmacology + Toxicology</td>
<td>SUM</td>
</tr>
<tr>
<td>General Physiology</td>
<td>KyoU/GU/ACA</td>
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<tr>
<td>Instrumental Techniques</td>
<td>UsdeC</td>
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<td>Biophysics</td>
<td>UKP</td>
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<td>Pharmacognosy</td>
<td>SUM</td>
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<td>Phytochemistry</td>
<td>VFU</td>
</tr>
<tr>
<td>Pharmacy Administration</td>
<td>SUM</td>
</tr>
<tr>
<td>Polymer Technology</td>
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</tr>
<tr>
<td>Biopolymers</td>
<td>TMRC</td>
</tr>
<tr>
<td>Tissue Engineering</td>
<td>HaU</td>
</tr>
</tbody>
</table>
pharmaceutical biotechnology courses in pharmacy curriculum, see (Table 1).

The percentage of pharmaceutical biotechnology courses in the total pharmacy education program was another important consideration of this survey. The percentage distribution of the replies showed a wide range of opinions: 5-10 % in Europe 10-20 % in Asia and 5-10 % in USA. This may be related to the approach and involvement of the respondent country at the industrial and academic level in pharmaceutical biotechnology.

Suggested essential topics before taking pharmaceutical biotechnology courses can be classified under 16 main topics (Table 2). The topics which were suggested the most were as follows: Biochemistry, Biology, Microbiology, Immunology, Basic Pharmaceutics and Chemistry.

The ultimate objective of all biotechnology research is the development of a commercial product. A variety of basic scientific disciplines contribute to biotechnology to generate different commercial products including drugs [8], vaccines [9,10] and diagnostics [11]. This is likely why these suggested topics were found to be essential for pharmaceutical biotechnology. In fact, basic and applied research in pharmaceutical biotechnology work closely together to improve quality of healthcare. For example, Problems faced in the production stage can after be solved with the support of the basic research.

The suggested categorization of topics for pharmaceutical biotechnology teaching in undergraduate courses of pharmacy education were as follows:

Main Topics
1. Proteins
2. Vaccines
3. Genomics
4. Recombinant DNA Technology
5. Monoclonal Antibodies
6. Fermentation and Cell Culture
7. Analytical Techniques Commonly Used in Biotechnology
8. Human Somatic Cell Culture
9. Regulatory and Compendial Aspects of Biotechnology Products

The results of the evaluation of the topics (Appendix II) as to their priority showed that "Proteins, Genomics, Vaccines, Recombinant DNA Technology and Analytical Techniques " were regarded as very important while "Fermentation and Cell Culture, Monoclonal Antibodies and Human Somatic Cell Culture" were evaluated as "important. Moreover, "Regulatory and Compendial Aspects of Biotechnology Products" were found to be important by most of the respondents. Respondents evaluated the suggested 9 main topics either as "very important" or "important". There were very few "less important" evaluations for all of the topics, which is an indication that the proposed topics seem to be regarded as realistic and critical by most respondents. Protein pharmaceuticals are today's most important pharmaceutical biotechnology products and genomics an emerging field, thus explaining the prioritization of these two topics. It is important to notice that the topic "Regulatory and Compendial Aspects" was rated as very important in the responses coming from USA.

Another important result that should be emphasized is the number of replies that came from industry in Europe and America (ten replies in total). This situation could be interpreted as a growing interest and emerging attention of industry to pharmaceutical biotechnology and biopharmaceuticals.

The importance of regulatory processes is related in part to the evaluation of the safety and efficacy of those products as well as the control of appropriate administration for each indication.
APPENDIX II
SUGGESTED CONTENT FOR UNDERGRADUATE TEACHING PROGRAM OF PHARMACEUTICAL BIOTECHNOLOGY IN PHARMACY FACULTIES

I. PROTEINS
1.1. Protein Structure
1.2. Protein Biosynthesis
1.3. Protein Modification
1.4. Protein Stability
1.4.1. Chemical Instability of Proteins
1.4.2. Physical Stability
1.5. Proteins as Biological Response Modifiers
1.6. Use of Transgenic animals in Protein Production
1.7. The Formulation of Proteins and Peptides
1.7.1. Routes of Administration Available for Proteins and Polypeptides
1.7.1.1. Oral Absorption of Proteins
1.7.1.2. Injectable Products
1.7.1.3. Rectal and Vaginal Delivery
1.7.1.4. Dermal and Transdermal Drug Delivery
1.7.1.5. Nasal Absorption and Delivery to the Lung

II. VACCINES
II. 1. Immunity and Protection
II.2. Vaccine Types
11.2.1. Toxoids, Polysaccharides, Proteins, Peptide Immunogen Formulations
11.2.2. Recombinant Microbial Vectors
11.2.3. DNA Vaccines

III. GENOMICS
111.1. Nucleotide Structure and Physical Characteristics
111.2. DNA Structure and Replication
111.3. Transcription

IV. RECOMBINANT DNA TECHNOLOGY
IV.1. Constructing Recombinant DNA Molecules
IV.2. The Uses of Recombinant DNA
IV.3. Examples of Applied Recombinant DNA Technology
IV.4. Engineering Protein Sequences

V. MONOCLONAL ANTIBODIES
V.I. The Production of Monoclonal Antibodies
V.2. Application of Monoclonal Antibodies

VI. FERMENTATION AND CELL CULTURES
VI.1. Types of Fermentation
VI.2. Types of Bioreactors
VI.3. Scaleup
VI.4. Cell Culture Types
VI.5. Protein Expression Systems
VI.6. Upstream Processing
VI.7. Product Purification

VII. ANALYTICAL TECHNIQUES COMMONLY USED IN BIOTECHNOLOGY
VII.1. Instrumental Analysis
VII.2. Separation Methods
VII.3. Bioassays
VII.4. Immunoassays

VIII. HUMAN SOMATIC CELL GENE THERAPY
VIII.1. Ex Vivo Gene Therapy
VIII.2. In Vivo Gene Therapy
VIII.3. Antisense Therapy
VIII.4. Polymerase Chain Reaction (PCR)
VIII.5. Gene Therapeutics

IX. REGULATORY AND COMPENDIAL ASPECTS OF BIOTECHNOLOGY PRODUCTS
IX.1. Regulating Use of Biotechnology
IX.2. Patenting Biotechnology Inventions

This is intended to protect the public health and to provide a regulated path for new products to reach the pharmaceutical market. The FDA (Food and Drug Administration) was the first institution assigned to regulating biotechnology products [12-14]. The EC is proceeding towards a single market and currently approval processes for biotechnology drugs are under consideration [15,16]. In Japan regulatory requirements are different less stringent [17]. As new technical innovations are introduced, and the number of biopharmaceutical products is growing tremendously researchers have focused on the international standardization.
of the production and the control procedures for biotechnology derived products. As a result, several guidelines about the preparation and control of biotechnology-derived drug products have been published in the last ten years.

Additional, data was also obtained regarding other topics which were suggested for inclusion in an education program are displayed in Table 3.

Suggestions coming from academic institutions and industry regarding such additional topics to the proposed program.

Topics suggested in the proposed program to be covered in pharmaceutical biotechnology courses were approved by the respondents of Europe, Asia and America, but further suggestions came from industry in the USA (Table 3).

Suggestions from industry included "ISO 9000 Standards and More Extensive Regulatory Affairs" topics related to manufacturing of high quality pharmaceutical products.

On the other hand, suggestions related to transgenic animals and biotechnological production of small molecules as antibiotics, vitamins and steroids seem to be very critical.

Some of the recommended topics coming from the respondents such as gene / gene therapy, DNA structures and DNA replication are already present under the suggested content (Appendix II). Recently great interest has been focused on the above mentioned topics [18,19].

The final emphasis was on academia and industry perspective to collaborate in a pharmaceutical biotechnology program. From the academia and industry collaboration aspect in pharmaceutical biotechnology the recommendations were centered around; apprenticeship in industry, research training in industry, summer school in industry. 33 of the respondents approved 75:25 (academia/industry) ratio for this collaboration, 7 of them suggested 50:50 while 3 of them responded as 25:75 and the rest providing no response. In addition to this evaluation, further suggestions came from some of the respondents in

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**Table 3. Suggested Additional Topics to be included in Pharmaceutical Biotechnology Courses**

<table>
<thead>
<tr>
<th>AMERICA</th>
<th>Additional Topics</th>
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</thead>
<tbody>
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<td>• MRCC</td>
</tr>
<tr>
<td></td>
<td>• Bioencapsulation</td>
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<tr>
<td></td>
<td>• Biotechnological Immobilization</td>
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<td></td>
<td>• Artificial Cells</td>
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<tr>
<td>U.S.A.</td>
<td>• Bio</td>
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<tr>
<td></td>
<td>• ISO 9000 Standards</td>
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<tr>
<td></td>
<td>• More Extensive Regulatory Affairs</td>
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<tr>
<td></td>
<td>• Quality Assurance / Quality Control</td>
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<td></td>
<td>• More Emphasis on Process of Drug Development and Approval</td>
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<td></td>
<td>• Molecular Diversity, Combinatorial Chemistry</td>
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<td>• Bioinformatics</td>
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<td>• Bioanalytical Laboratory</td>
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<td>• Robotics in Testing Laboratories</td>
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<tr>
<td></td>
<td>• Team Based Approaches</td>
</tr>
<tr>
<td></td>
<td>• Management Skills</td>
</tr>
<tr>
<td>RW Johnson</td>
<td>• ADME/PK Considerations</td>
</tr>
</tbody>
</table>

**EUROPE**

**Czech Republic**

| • UKP           | • Antibiotics Production                       |
|                | • Alkaloids Production                         |
|                | • Hormones Production                          |
|                | • Amidicoids + Organic Acids Production        |
|                | • Vitamins Production                          |
|                | • Enzyme + Polysaccharides Production          |

**Germany**

| • UB            | • Transgenic Plants                            |
|                | • Transgenic Animals                           |
|                | • PCR, Gene Diagnostics                        |

**Italy**

| • UUr           | • Pharmacokinetics + Pharmacodynamics of Peptides/Proteins |

Europe (Krka, Slovenia and HeU, Israel) as follows: Conferences, lectures and/or courses given by experts from industry, experimental work
for diploma or Ph.D. thesis, 2-3 years of specialization schools run by industry and controlled by universities.

CONCLUSION

Data from various pharmacy faculties and related companies from USA, Europe and Asia was received and evaluated. All of the respondents recommended the inclusion of pharmaceutical biotechnology courses in the curriculum of pharmacy faculties. Biochemistry, Biology, Microbiology, Immunology, Basic Pharmaceutics and Chemistry courses were the most suggested topics to be covered before taking pharmaceutical biotechnology courses. In the pharmaceutical biotechnology program which was suggested by the authors:

"Proteins, Genomics, Vaccines, Recombinant DNA Technology and Analytical Techniques" were evaluated as "very important" topics by respondents whereas "Regulatory and Compendia! Aspects of Biotechnology Products" was evaluated as an important topic by most of the respondents. Additional topics such as:

- ISO 9000 Standards
- Bioinformatics
- Robotics in Testing Laboratories

were suggested from Industry (USA) to be included in any pharmaceutical biotechnology teaching program. Meanwhile, faculties from Europe suggested topics such as small biological molecules such as antibiotics, but also transgenic plants and animals.

The outcome showed that educational efforts in educating qualified staff in this rapidly growing field of pharmaceutical biotechnology are encouraging. Training of students in this area will be critical for the future scientific development of the Biopharmaceutical Industry. It is essential that Pharmacists become familiar with biotechnology-derived products as they are with other drugs.

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