

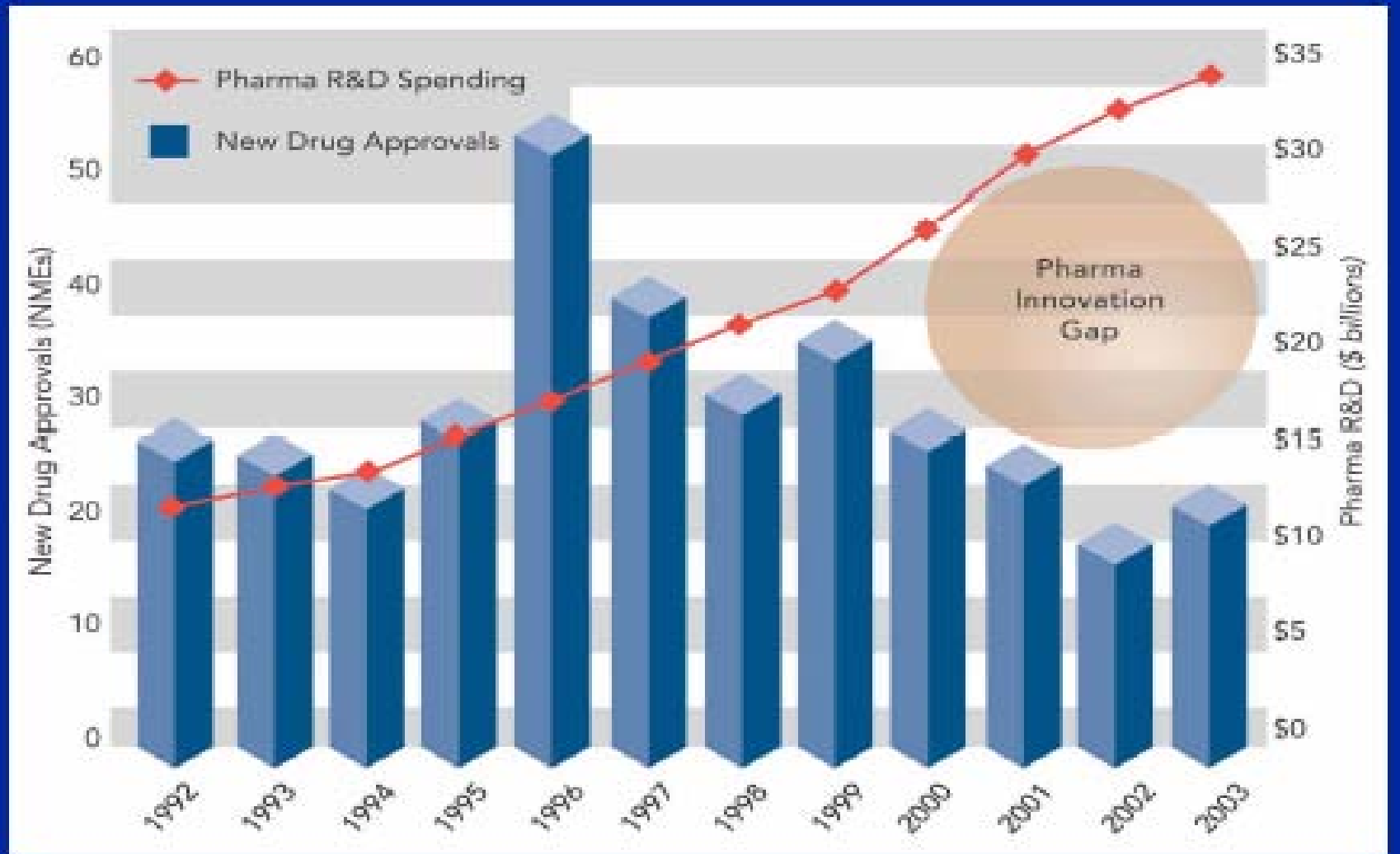
Future Specialisation for Pharmacists in Industry

JANE NICHOLSON

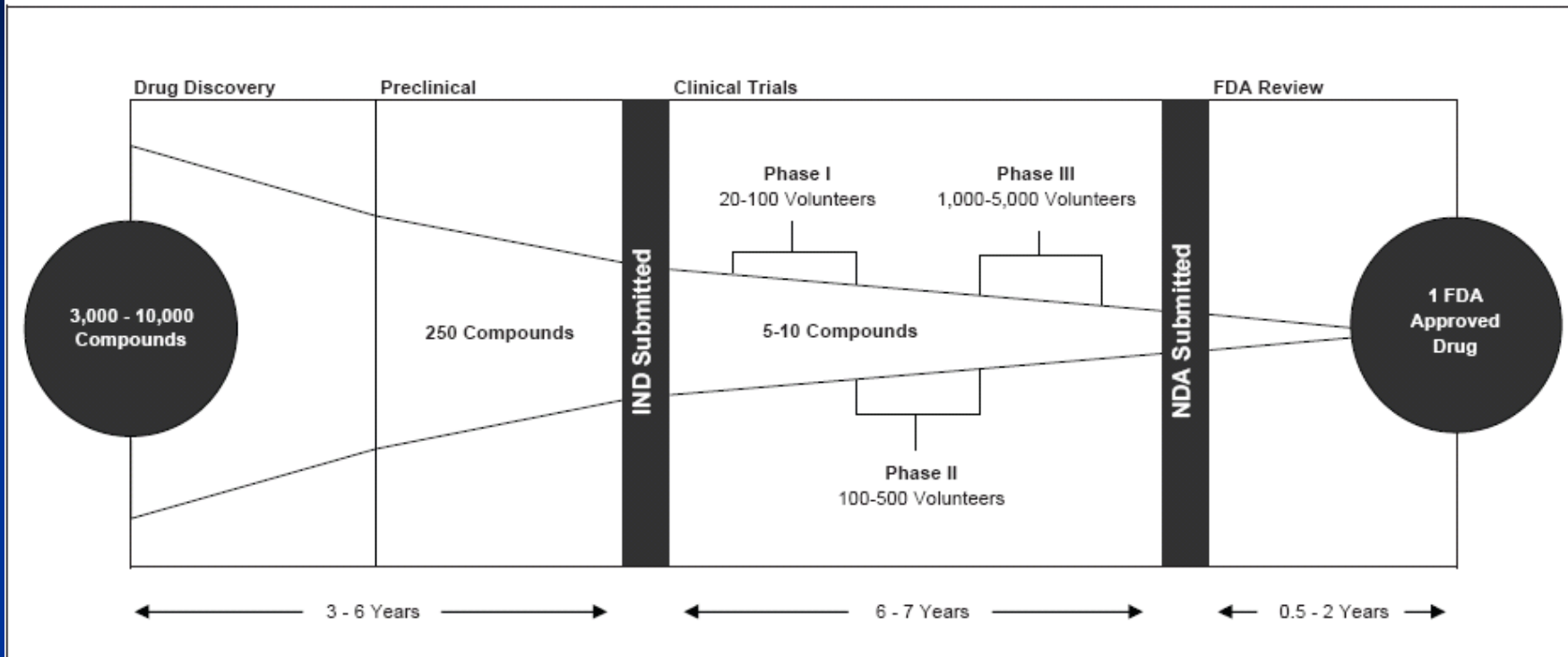
Executive Director

European Industrial Pharmacists Group
(EIPG)

Innovation gap...



Number of Compounds to Produce a New Drug



Source: PhRMA and FN estimates

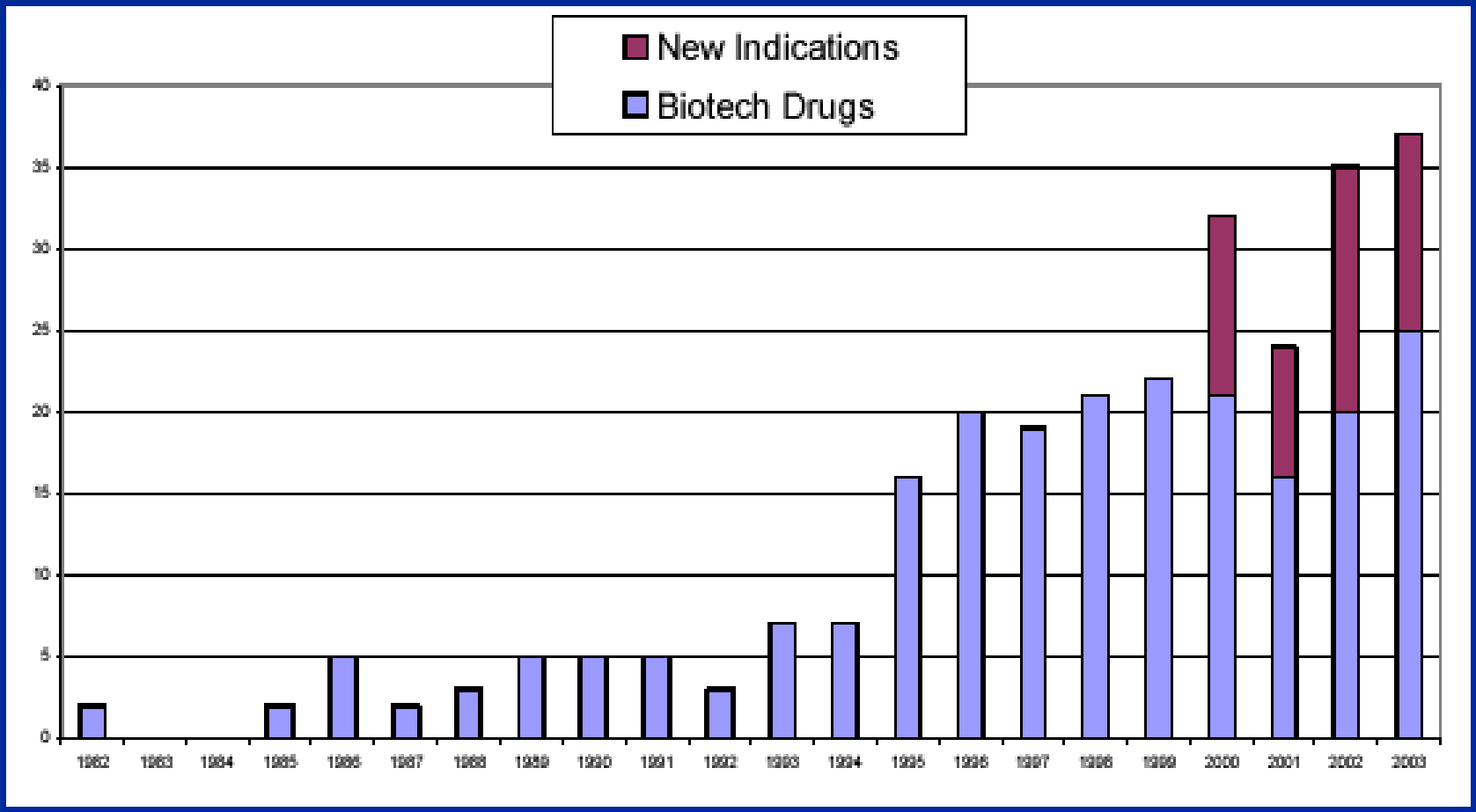
Cost is now ~ £ 700-1billion

Success Rate 1 in 10,000

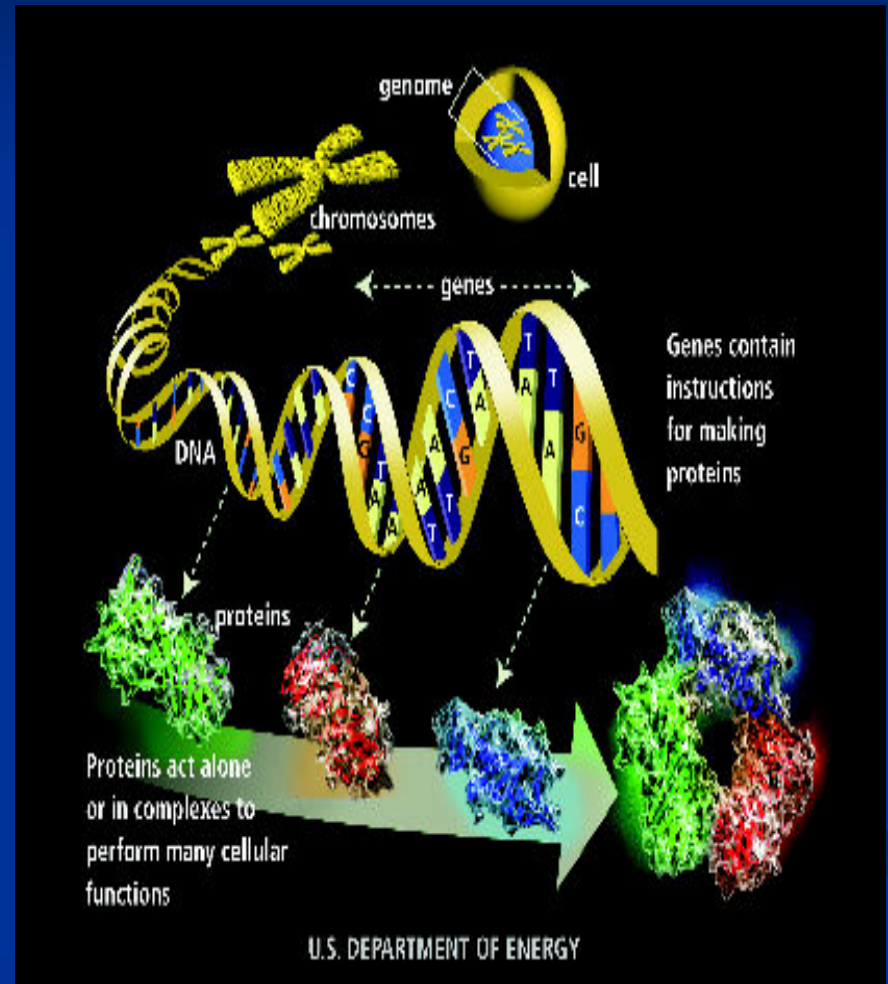
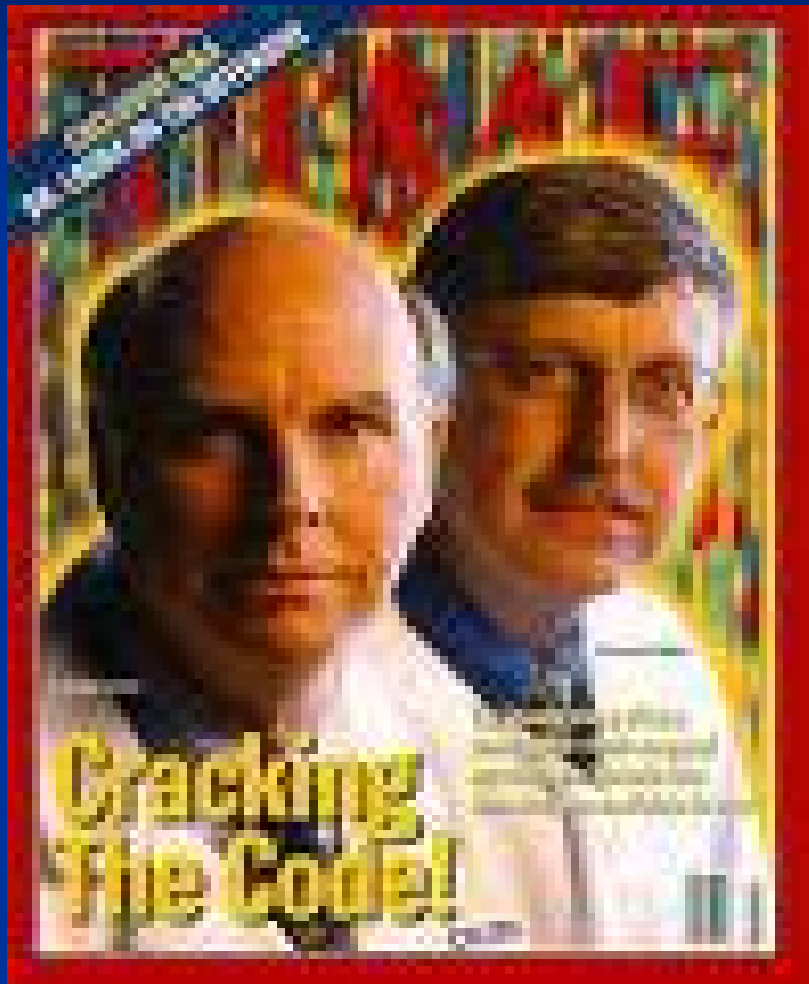
“By 2010 most pharmaceutical research will be undertaken by biotechnology companies”

Deutsche Bank

Number of biotech products approved



The Human Genome Promise



Outsourcing

In the future, any function that can be done more cost efficiently outside of the organization will be outsourced.

At least 10 of the largest pharmaceutical companies outsource aspects of medicinal chemistry to developing countries.

Why Offshore to India?

India is the most popular destination for offshore outsourcing, for a number of reasons.

■ **Cost**

- *Highly educated workforce at 10-20% of European cost.*
- *Even when outsourced to a vendor, savings can be 30-40%.*

■ **Quality**

- *"Come for the cost, stay for the quality" is becoming a cliché, but it is a valid observation.*
- *World leader in standards such as SEI-CMM.*

■ **People**

- *2.1 million new graduates each year.*
- *0.3 million post-graduates each year.*
- *Skilled available people at all levels.*
- *Graduates have all studied in English.*



The Continuing Evolution of the
Pharmaceutical Industry:
Career Challenges and Opportunities

December 2007

Michael Steiner, CFP®, CPA et al

- The need to increase productivity will lead companies to pay more for those individuals who have detailed, essential expertise as well as those persons who are capable of managing the extremely complex aspects of their businesses. Most of the remaining positions will be outsourced over time.

Technology Review- Vision 2010

- Challenge – To achieve the right balance between education in the basic sciences and training in the emerging areas of science and technology.
- Challenge- Current shortage of specific personnel in bioscience including molecular biologists, biotechnology, genomics, bio-informatics as well as chemists and pharmacists

Technology Review- Vision 2010

- Need for new combinations of studies to reflect future needs eg. Bioscience plus IT/mathematics; Biology plus entrepreneurship; Pharmacy plus engineering; Pharmacy plus health economics
- Pharmacists need more education in basic biological sciences
- The amount of business, marketing and advertising in the curricula must be increased if graduates are to perform their R and D functions successfully

In terms of core skills – general capabilities that cut across all scientific disciplines, members were concerned about :

- Basic mathematical capability
- Practical skills
- Ability to apply scientific and mathematical knowledge

In terms of core disciplines –concern about substantive skills deficit in biomedical sciences, many of which are at the heart of translational medicine or are key to the commercialisation of research, namely :

- clinical pharmacology / experimental medicine;
- drug metabolism and ADME1;
- pharmacokinetics, pharmacodynamics and modelling;
- in vivo sciences and supporting animal technologies;
- chemical and process engineering;
- statistics and
- computational chemistry.

Skills needs for Biomedical Research (ABPI report 2008)

Pharmacists work across the industry in areas such as the assessment of safety and efficacy of new medicines, the formulation of medicines (e.g. skin patches, pills, targeted release) and may be responsible for the release of medicines to the market.

- - There is a pool of good graduates, but this is diminishing as pharmacy degrees reduce their industry focus and basic science content
- - Bringing pharmacists in to the industry is hard; retail and hospital pharmacy may be more attractive
- - Recruiting people with experience is difficult; there is increasing recruitment from the EU
- - Formulation is still a particular problem; pharmaceuticals and pharmaceutical technology skills are weak

Skills needs for Biomedical Research - 2008 ABPI Survey of 30 companies in Britain for Pharmacy :

Quality of candidates; Number of candidates; Future of the discipline; all considered to be a “medium priority concern” requiring action.

Lack of Post-Docs considered high priority requiring immediate action

- Graduate
- PhD
- Post-Doc

Innovative Medicines Initiative- Selected Projects Training 12 - 15

■ European Medicines Research

Training Network Expected outcome: a European biopharmaceutical research training platform providing a sustainable academia-industry cross –disciplinary approach to efficient organisation of training courses on emerging science and technologies across Europe

EIPG defines

MAIN AREAS OF EMPLOYMENT FOR PHARMACISTS IN INDUSTRY

- Research and Development
- Quality Assurance and Analysis
- Manufacture
- Regulatory Affairs
- Clinical trials and Pharmacovigilance
- Marketing and Sales and Sales Training
- Product/Medical Information
- Wholesaling
- General Management

Seven Skill Sets Necessary to Operate in the Pharmaceutical Industry of the Future

Ability to Manage Decentralized Intellectual Capital Resources

Ability to Work in Joint Ventures and Across Divisions, Cultures and Countries

Ability to Integrate an Understanding of Intellectual Property Laws, Scientific Expertise and Business Strategy

Ability to Spur Creativity While Managing Commercially

Knowledge and Insight on the Decision-Making Dynamics of Payers

Expertise in the Functioning and Decision-Making of Regulatory Agencies

Human Resource Skills to Help Transform Pharmaceutical Companies

**The Continuing Evolution of the
Pharmaceutical Industry:
Career Challenges and Opportunities
Michael Steiner et al December 2007**

DRAFT DOCUMENT
Guidelines for the
activities / competence of
the industrial Pharmacist

Pr P. TCHORELOFF

Faculté de Pharmacie de Châtenay-Malabry

**Work conducted for the "Commission Nationale de
Pédagogie des Études de Pharmacie" CPNEP**

These guidelines encompass 15 skills (1)

- Skill 1 in the field of the **search for new compounds**
- Skill 2 in the field of **galenic and industrial development**
- Skill 3 in the field of **analytical development**
- Skill 4 in the field of **non-clinical development**
- Skill 5 in the field of **clinical development**
- Skill 6 in the field of the **industrial production of drugs (manufacture / packaging / quality control / distribution)**
- Skill 7 in the field of **quality**
- Skill 8 in the field of **regulatory affairs and registration**
- Skill 9 in the field of **marketing, information and distribution of drugs and other healthcare products**

Each skill corresponds to one of the sectors / assignments open to industrial pharmacists

- Skill 10 in the field of **the economic, political, social and regulatory environment of the drug industry**
- Skill 11 in the field of **communication**
- Skill 12 in the field of **administration**
- Skill 13 in the field of **team management**
- Skill 14 in the field of **professional training**
- Skill 15 in the field of **public health**

Skills common to the various assignments

Key Regulatory Competencies

TOPRA lifelong learning 2009

- IT Competencies: word processing, spreadsheets, presentations, project management, documentation management systems, publishing/eCTD
- “Soft Skills”: negotiation , influencing and presentation skills, team working in a global environment, project management and strategic thinking, time management, leadership skills, performance management, marketing for regulators, crisis management

Belgium Brain storming session

What are the changes in the Pharmaceutical Industry and what is the impact of these changes on industrial pharmacists

- Increased importance of pharmacovigilance/risk-benefit analysis/regulatory affairs and strategy/electronic document management
- Knowledge of economy/management/finance/process analysis/communication and customer liaisons skills
- Knowledge of intellectual property rights/project management/pharmacoeconomics
- Specialization is indispensable

EUROPEAN INDUSTRIAL PHARMACISTS GROUP (EIPG)

Questions on industrial aspects of
post-registration pharmaceutical
education distributed March –April
2009

QUESTIONS

- Provide an outline of post-registration courses currently available for Masters, Diploma or Continuing Education courses for pharmacists working in industry .
- Do these current courses meet the skills required for an industrial career in the 21st century? If not, what are the gaps?
- Are PhDs undertaken in your country with pharmaceutical companies advising academia on potential subjects for research ? (as well as those where academia is following their own research)

Responses received from :
Belgium, Bulgaria, Czech,
Denmark, France, Germany,
Greece, Great Britain, Italy,
Latvia, Malta, Netherlands,
Sweden

SWEDEN Modular training courses in clinical trials with exam as CT Manager

Theory -Basic and advanced courses in clinical trials including GCP and basic knowledge of statistics in clinical trials.

General knowledge (advanced level in 2 courses) and study of prescribed literature of the following:

- Clinical trial design and protocols; Data management and analysis; Clinical trial reports; Adverse events management
- Financial and other agreements in clinical trials; Pharmacokinetics; Toxicology; Health economy in clinical trials
- Clinical epidemiology; Quality of life in clinical trials; Clinical trials in specific disease areas; GCP audits and inspections
- Ethics in clinical research; Theory of biological sciences

Practical Experience

■ **Three years, full or part time (minimum 75%) work with clinical trials including active participation in:**

- Compilation of documentation for trial application to Medical Products Agency and/or Ethics Committee or Design of flow chart for a clinical trial; Study site planning and preparation of a clinical trial
- Planning and conduct of investigators meeting or study site information activities
- Initiation of a clinical trial or organisation and conduct of a trial at the study site
- Monitoring according to GCP (including Source Data Verification) or collaboration with monitors
- Completion of a clinical trial (including drug accountability).

Active participation in at least 4 of 8 trial related activities which include handling of adverse events, care of study participants; budget/financial agreements, authoring trial protocol or report

Swedish Academy of Pharmaceutical Sciences (Läkemedelsakademin)

Pharmaceutical Industry Advanced Training PIAT, Manchester University, England

- Developed with industry for scientists working in product development, manufacture, quality assurance
- For each module, students complete exercises, a written assignment, attend a workshop and an examination session at the University. MSc students must complete a dissertation.
- Modules include Industrial pharmacy, Clinical trials, Toxicology, Pharmaceutical business development and Licensing, Pharmaceutical microbiology.

Germany Post-Graduate “Specialization”

- Framework + general content defined by federal pharmacist association
- Locations and trainers to be approved by regional chambers
- Course is 120 seminar hours within 3 years
- **“Expert Pharmacist for”**...Community Pharmacy-Clinical Pharmacy-Drug Product Information-Pharmaceutical Technology-Pharmaceutical Analysis-Toxicology and Ecology-Theoretical+ Practical Education-Public Health Affairs-Clinical Chemistry
- **Additionally and sometimes only regionally offered:** Nutrition, Health Consulting, Oncology, Natural Therapies+ Homeopathy, Geriatrics, Home Care, Education.

There are a large number of other specialist courses such as “Economics for Pharmacists”

“Pharmacists have a unique profile: Generalists, team, customer and “applied science” oriented, medium to bridge natural science, medicinal, regulatory and technical requirements and processes.” *Dr. Thomas Schneppe, Bayer HealthCare, 2008*

Italy

Post-graduate Masters Courses

Organised by our EIPG member ASSOCIAZIONE FARMACEUTICI INDUSTRIA (A.F.I.) with Farindustria (Association of Pharmaceutical Entrepreneurs) , Tefarco (Association for Technical Innovation in the Pharma Sector) and C.R.S. (Controlled Release Society) :

- 1. Master in “*Pharmaceutical Technology and Regulatory Affairs*”, at the Universities of Parma, Pavia, Sassari, Perugia, (from January through June 2008)
- 2. Master in “*Industrial Pharmaceutical Technologies*” at the University of Rome (from January through June 2008)
- 3. Master in “*Preformulation and Pharmaceutical Development*”, at the University of Pavia (from March through July 2008)
- Special courses have been organised in Rome, on request of Italian Health Authorities (AIFA) for the inspectors training.

Belgium

- For the title Industrial Pharmacist, the Schools of Pharmacy in Belgium run “Advanced Masters” in industrial pharmacy – full time 1 year.
- More popular than 1 year training in company for title of Industrial Pharmacist as companies expect Advanced Masters.

Philippe Van der Hofstadt, CEO, B & C Group s.a.

Bulgaria

After graduation, a 3 year post-graduate specialisation can be undertaken in:

Pharmaceutical analysis

Pharmaceutical technology

Industrial pharmacy

However, interest in any specialisation is extremely low, (one or two students per year.)

The main problem is that the factories are far from the big cities and the salaries there are not attractive, so there is total dissonance between needs and supply of industrial pharmacists

Greece

- **Athens**- Masters in Industrial Pharmacy, 2 year course including 6 months research project
- **Thessaloniki**- Masters in Pharmaceutical Sciences
- **Patras**- Post-graduate diplomas if specialisation in:
 - Industrial Pharmaceutics and Drug Analysis
 - Pharmaceutical Chemistry-Natural Products
 - Molecular Pharmacology - Clinical Pharmacy
 - Pharmaceutical Biotechnology and Biomedicine
 - Pharmaceutical Marketing
- In addition some specialised courses are available such as Total Quality Management, Pharmacoeconomics, Pharmaceutical Marketing .

Denmark

Although 65% of pharmacists in Denmark are employed in the Pharmaceutical and Allied Industries, the Faculty of Pharmacy, University of Copenhagen runs courses:

Master in Drug Management

Master of Industrial Drug Development

Master of Pharmaceutical Regulatory Affairs

“There will always be specific needs for additional learning, based on specific job content that is not included in the pharmacy education.” Michiel Ringkjøbing Elema, Pharmaceutical Development, H. Lundbeck

Conclusions

- Flexibility! Post-registration needs vary, in part due to differences in undergraduate courses in the countries of Europe
- Shortage of skills in emerging science and technology, proteomics, genomics, xenotransplantation. More specialist courses and post-docs required.
- To perform successfully, pharmacists need to understand business management, economics, intellectual property, marketing and communication

Suggestions

- Joint Ventures- Schools of Pharmacy should team up with Departments of Business Studies, Law, Health Economics, so that pharmacists can relate these specialist post-registration courses to their role in pharmacy.
- the ability to be exposed simultaneously to the industrial environment and the higher level training makes for an optimum blend of conditions for **part-time or distance learning Advanced Masters Courses.**