The PAT Concept in Relation to Quality by Design & Current Developments in the EUFEPS PAT Science Network

The rate of entry of new drug products onto the market has decreased, while the costs have increased. Obviously, both drug development and drug manufacturing are challenged. Without doubt, good quality products reach the patients, securing identity, strength and purity. However, the way this quality is achieved, today, may not be as fast, efficient and low-cost as one would like it to be.

There are challenges

Looking back, the cost of drug manufacturing has not really been in focus, especially when compared with other areas such as clinical development and marketing. But times change. The Price Waterhouse Coopers report, in 2001, comparing pharmaceutical manufacturing with other industries, was claiming that effectiveness was not challenged and rework and batch failure not properly addressed in the pharmaceutical industry. In the report, it was also suggested that, due to the way pharmaceutical development were set up and regulated, 50% of production costs were locked in before Phase III studies begin, revealing process inefficiencies.

A critical look at the situation would indicate that:
- The scientific knowledge is not always built into the product and process;
- The science is not always shared with regulators and the common ground for understanding is missing;
- The drive for continuous innovation, rationalisation and increased efficiency of drug manufacturing is assumed to be limited due to rigorous regulatory burdens; and
- The quality control does not give the optimal information.

New agenda

However, time and cost reduction is now high on the agenda. Pressure comes from society to reduce health care costs as well as from internal company efforts to increase efficiency. It is a common understanding that drug development, has to become faster, but it is now obvious that also the pharmaceutical manufacturing must be more efficient. There is a need to increase process robustness, reduce lead times, reduce unnecessary testing etc. and it is an advantage that these efforts start during development. Quality by Design is a concept to support this evolution as illustrated in the figure below.
**Quality by Design related to PAT**

Efforts and discussions, since the beginning of this century, have now resulted in directions given in ICH guidelines Q8 and Q9. Q8 deals with the Pharmaceutical Development including Quality by Design, with focus on drug product development. Q9 deals with Quality Risk Management, a systematic process for the assessment, control, communication and review of risk to the quality of the drug product across the life cycle. A third guideline, Q10, is under way covering the Quality Systems, complementing existing GMPs to facilitate improvement in pharmaceutical manufacturing. These documents are high-level guidelines giving directions and not details, which means that there is room for interpretation and development of the ways to approach this. One intention is to reduce the regulatory hurdles for continuous improvement and new innovations.

A current understanding of how to define Quality by Design can be found in ICH Q8. “Quality should be built in by design” and “the information and knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the Design Space”. The design space can be seen as the result of the collected knowledge that gives a scientific ground for the process and product and how to control it. It is expressed in the following way in ICH Q8 “The multidimensional combination of input variables (e.g. material attributes) and process parameters that have been demonstrated to provide assurance of quality”.

If the company share this Design Space knowledge and obtain acceptance with health authorities, one can utilise the statement in Q8, which says that moving around within the Design Space is not considered a change and does not need regulatory approval. This will lead to regulatory relief, whilst still maintaining assurance of quality.

It is obvious that the science and understanding that is behind the Quality by Design has to be supported by measurement, analytical data, evaluation and interpretation. This is where Process Analytical Technology (PAT) comes into the picture. PAT is defined (Q8) as: “A system for designing, analysing and controlling manufacturing through timely measurements (i.e. during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality”.

The figure below schematically describes PAT as an “enabler” for Quality by Design. The conclusion is that PAT provides not only the tools and systems for manufacturing control but also for deeper understanding of the process science.

**PAT Tools and implementation**

The introduction of advanced measurement in the process should be preceded by a Quality Risk Assessment to evaluate the criticality of the different process steps. By this action, it is possible to capture where PAT tools should be introduced and thereby obtain a so-called “lean PAT” approach.

It is important to understand the underlying principles of the techniques and their capability. In many cases we are looking for continuous quantitative measurements in solid-state materials, which can be complicated. The research work may admit a more complex, specialised equipment while in the large-scale manufacturing situation robust simple-to-handle equipment is the optimal solution. The concept of fit for purpose should be kept in mind. Near infra red (NIR) spectroscopy is one of the more frequently used PAT techniques being fairly robust and general. It can be applied to measure blending, moisture, content of active etc and be used either “in-line” or “at-line”.

Technical innovations in the analytical chemical area, advancement in computerized calculations, imaging, presentation of data etc. have stimulated the development of advanced PAT tools. However there is still a great need for robust and commercially available systems.

**Variety of cases**

In summary, the final purpose with Quality by Design and PAT is not necessarily the same in all cases. In many cases the process robustness is the main goal including process understanding, lead-time reduction and early detection of process deviations. In rare cases the reduction of end point quality control utilising Real Time Release (RTR) or rather Real Time Quality Control (RTQC) is an attractive option. Finally, the claiming a Design Space and the regulatory relief that this may give could be the purpose of the Quality by Design work.

Concluding that PAT is the enabler for Quality by Design we find that the technical development and science behind PAT has to be further encouraged. This is leading into the second subject of this article, the EUFEPS European Network on PAT Sciences.

**Collaboration developing**

There are a number of committees and networks active within EUFEPS and through the Committee of Industrial Research Relations (CIRR) the initiative of PAT was started. At EUFEPS 2004 (the European Congress of Pharmaceutical Sciences), on: “New Safe Medicines: Towards Mechanistic...”
Prediction”, one of the sessions was devoted to PAT under the heading “Revolution in Science Driving Process Analytical Technology”. Those participating decided to create a “European Network for PAT Science” to stimulate and initiate scientific approaches and interactions as well as education and training. EUFEPS agreed to provide a home for this Network as well as to help with communication and organisation of meeting and courses.

A Steering Committee was appointed with members from both industry and academia. The guidelines for the Network can be summarized in the following way:

- PAT is an integral component of the EUFEPS theme ‘New Safe Medicines Faster’
- Encourage, stimulate and initiate PAT scientific approaches and interactions in pharmaceutical sciences
- Initiate educational and training programmes in the field
- Act as a resource and debating forum to stimulate and promote fundamental scientific and engineering research and innovative approaches in PAT
- Approach these issues from a multi-disciplinary perspective
- Communicate and establish dialogue with all stakeholders in PAT in the EU, and beyond.

The Network coordinated EuPAT1 in Gothenburg, Sweden, in November 2006, with ISPE Nordic Affiliate (International Society of Pharmaceutical Engineers) and in collaboration with EFB (European Federation of Biotechnology). This is expected to become a yearly meeting in November-December and, hopefully, the meeting point for PAT scientists in Europe. Indeed, the EuPAT2 will take place in Copenhagen, Sweden, on November 14-15, 2007. For invitation and programme of EuPAT2, consult the EUFEPS Online (www.eufeps.org). In a recent discussion paper, the mission of the EuPAT Conference Series is presented in more detail (“EuPAT: An initiative to promote progress in the science underpinning PAT”, S. Folestad, P. York, R. Bro, European Pharmaceutical Review, 81-86, 3(12), 2007). The Network will also support other PAT congress programmes, like e.g. the Pharmaceutical Science Fair & Exhibition in June 2009 in Nice, France.

The Steering Committee has provided input to the Innovative Medicines Initiative (IMI) and the European Commission 7th Framework Programme. Education and training has, furthermore, been arranged for EMEA inspectors and assessors, and plans are under way to continue with such an education programme. Related organisations and stakeholders have been approached for co-operation, including ISPE and EFB. The Network has also established contacts with the EMEA and has approached EFPIA as well.

There are a number of conferences dealing with Quality by Design, the high level concept and the regulatory issues and interactions. The intention with this EUFEPS European Network of PAT Sciences is to give Europe a meeting place for PAT Science.

**In conclusion**

Current visionary tasks for the PAT Science Network in Europe include:

- Maintaining a ‘neutral’ pan-European forum for PAT science
- Delivering innovative ‘design science’ for formulation, process and product quality
- Establishing multidisciplinary scientific research networks
- Providing educational and training programmes to provide a skill base for all PAT stakeholders

Peter York, Staffan Folestad, Anna-Maria Tivert, Hans H Linden
EUFEPS European PAT Science Network

---

**Xceleron and Organon sign Microdose Agreement**

EUFeps is a member of the EUMAPP consortium (www.eumapp.com), which aims to gather early clinical pharmacology information through microdosing techniques. Recently, Xceleron and Organon announced one such project.

Xceleron has announced a collaboration with Organon, the human healthcare business unit of Akzo Nobel, on a three-compound human microdose study focusing on candidate selection for further clinical development. The 3 selected drug candidates are all compounds that have emerged from Organon’s extensive gynaecological research and development activities.

The purpose of the human microdose study is to quickly assess all important pharmacokinetic properties of the compounds whilst confirming the scalability of the microdose to pharmacological dose for these compounds. Xceleron will use its ultra-sensitive Accelerator Mass Spectrometry analytical technology to determine human plasma concentrations after microgram administration of the drug candidates. “Increasingly, leading pharmaceutical companies are adopting Xceleron’s new drug development strategies to maximize data on compounds in the exploratory clinical development phase” observed Xceleron’s founder and CEO, Professor Colin Garner.

David Nicholson, Executive Vice-President, Research & Development of Organon commented: “given previous positive experience with Xceleron and its enabling technology we have commissioned this microdose study to examine important pharmacokinetic parameters in humans, in order to aid confirmation of the best candidate for further development”. Commenting on the value of the innovative human microdose approach he added: “the most compelling reason for using human microdosing is the speed with which we can gain results from human studies to make pivotal decisions”.

---
Progress towards the Innovative Medicines Initiative (IMI)

The Innovative Medicines Initiative (IMI) is becoming a reality through the European Union (EU)

Concept agreed
During Spring 2007, the Commission got all their consultations and paperwork in order, to being able to deliver the legal foundation for the “Joint Undertaking” (JU) on 15th May to the Council and EU Parliament. The JU, a concept that is new to the EU, provides a way of creating new partnerships between publicly and privately funded organisations involved in research, focussing on areas where research and technical development can contribute to European competitiveness and quality of life.

The Member States, and their ministries have received the paper positively, but have asked for clarification regarding the role of the Member States and the “Scientific Committee”. The role of the latter are purely consultative; all power lies in the hands of the “Board”, consisting of equal number of representatives from the Commission and European Federation of Pharmaceutical Industries and Associates (EFPIA) (see Figure). At the meeting of the “Member State Group” on 19th June 2007, the Commission answered the questions about securing sufficient transparency of the process. The Member States seem satisfied with the procedures the Commission will implement to secure balanced influences from the “Member State Group” and “Scientific Committee” on the procedures for generating calls for proposals and for allocating the money to the right consortia after open competition. The JU will make 2 billion euros available for competitive research over the next 7 years (see box).

The IMI Funding Principles specify a total EU contribution of 1 billion euros (€) for 2008-2015. In 2008, the Principles will cover research activities to a cost of 80 million €. By 2015, this will be 250 million € per year. The funding is 75% for direct and indirect costs, with 20% as a flat rate overhead. Management will be covered with 100% full time equivalents (FTE) in hours, plus travel and subsistence. For training activities, there will be 100% coverage for courses, implying FTEs in hours for teachers, and all fees for participants, facilities and equipment. Salary costs of trainees are not covered.

Procedures for calls
In short, the participating large companies will formulate the calls and at least two EFPIA companies must be involved in each project. The call will go public and consortia, excluding the parent companies, will be formed in response. The consortia submit their proposals, which are evaluated and placed in priority order. This ranking cannot be overruled in the subsequent second stage of negotiation, where the parent companies get involved to formulate the final full application, that is sent to a second peer review for final adoption, followed by the execution by the IMI Board.

In this way the companies have got their great wish fulfilled i.e. only to work on applications (plans) that will go through. The evaluation process is not yet in place; the important instructions for the evaluation criteria are lacking.

The evaluation is by peer review, based on
one round of calls per year. The Commission prefers to have “Standing Evaluation Panels” of 12 members, one for each of the four pillars: Efficacy, Safety, Data Management and Education & Training. They may be supplemented with ad hoc experts. These panels are elected for 2-3 years. In this way, continuity in the process is secured, something the Commission felt a need for. Furthermore, external assessment of the process, with reporting to the Member State Group, will be performed regularly.

Education and Training
This represents the fourth pillar described in the Strategic Research Agenda after efficacy, safety and knowledge management. The mission for the Education and Training (E&T) pillar includes;

• To build upon existing universities and higher education institutions in Europe by identifying Centres of Excellence within the various disciplines of medicines R&D, and to stimulate collaboration between these centres
• To provide E&T support to remove bottlenecks in the medicines R&D process
• To establish multiple public-private partnerships for graduate, doctoral and postdoctoral E&T
• To facilitate mobility between academia, industry and regulators

The proposed activities covers 60 PhD grants for each of 8 programmes in the following prioritised order;
• Integrated medicines development
• Ethics committee and patient organisation programmes
• Safety science programmes
• Other scientists within pharmaceutical R&D
• Pharmaceutical medicine professionals
• Regulatory affairs-based programmes
• Biostatisticians programme
• Bioinformatics and biomedical informatics programme.

Thus a total of 480 PhD grants will become available over the running period of seven years. These grants are provided 50% by IMI and 50% by industry, to a total of €120,000, plus a bench fee of €40,000 and €10,000 for conferences and industrial courses. For each of the 8 programmes, it is proposed that the IMI budget reserve money for 2 courses of 1 month duration with 26 participants to be organized in 4 regions in Europe.

IMI will work towards a European Medicines Research Academy (EMRA). This EMRA should consist of a set of Centres of Excellence. These Centres of Excellence and the courses they run will be selected based on a set of criteria, which are not yet defined, but will include a ‘human factor’.

Within IMI, a budget is reserved for a small coordinating office at a participating university.

IMI uses the Bologna standards: Bachelor 3 years, Masters 2 years, and PhD 3 years.

It is worth noting that the outline mentioned above is already 18 months old. During the summer 2007, discussion with the Commission and EFPIA will take place, and on 25th September 2007 the Member State Group will be consulted.

In this regard, EUFEPS has taken some actions. The Committee on Education and Training (CET) together with TI Pharma, other university representatives and an EFPIA representative Jörgen Dirach, got together on 29th June in Leiden, to discuss a pan-European effort preparing for the IMI initiative. IMI and EUFEPS have similar objectives: improving the level of pharmaceutical education and training in Europe. With IMI not yet up and running, EUFEPS in the initial stage supported by TI Pharma can make a start, preferably in such a way that lays the foundation for the IMI activities.

An inventory (or a map) of available quality courses in Europe has to be made. EUFEPS has a database, but it is not operational or up to date. This will be reactivated with a ‘push’ instead of a ‘pull’ principle. Organizations should keep the information in the database up to date, instead of letting the keeper of the database do so. A working group was chosen to work out a set of criteria, including the ‘human factor’, for listing courses in the database.

A next meeting was scheduled in September/October 2009.

Next Steps
The Commission now awaits the opinion of the European Parliament and the European Economic and Social Committee (December 2007) and the adoption by the European Council (January 2008). As soon as these are in place, the IMI Joint Undertaking will be set up and the first calls for proposals will be launched (February 2008), as they have been prepared beforehand. Projects should start in July 2008. In the meantime, our community can only consult the Strategic Research Agenda for research topics and reinforce relationships with industry to be prepared as much as possible. Both a top-down and bottom-up process is expected. Without doubt, the research directors within the EFPIA group will define the topics of the calls in the beginning of the programme, but later on, a bottom-up process will take place, where local initiatives and ideas will be channelled through the internal lines of the companies to appear as calls. Also, the Scientific Committee and the Stakeholder Forum can give input. Accordingly, I would encourage you to talk to your industry contacts about the IMI JU. Don’t expect that they are aware of its existence.

Finally – I, who have been in the process of preparing IMI for so long, cannot see any reason why it should go wrong now.

The IMI JU is on schedule - so better be prepared out there!

Ole J. Bjerrum

Core Elements
The Innovative Medicines Initiative will create a € 2 billion research programme over 7 years, jointly with the pharmaceutical industry. This programme will support the development of new knowledge, tools and methods to bring better and safer medicines quicker to the market.

The EU Framework Programme 7 will contribute € 1 billion, to go directly to small and medium enterprises (SMEs) and universities. These organizations will undertake research that serves the general, pre-competitive needs of the pharmaceutical sector. The pharmaceutical companies will match this € 1 billion by undertaking research and development projects with these SMEs and universities.
The peer reviewing process – the debate continues

In the June 2007 issue of this Newsletter, Daan Crommelin and Ole Bjerrum challenged the membership to put forward their views on the best way forward to achieve excellent peer reviews in Europe. The EUFEPS President was first to the keyboard.

Who is a peer?

Peer reviewing is important, but who is a peer? The problem of pharmacists by the fact that in many national statistics, in many funding agencies and in many scientific academies: "pharmacy" appears only - if at all - as a sub-discipline of chemistry, biology, molecular biology, pharmacology, medicine, botany, physical chemistry, etc. This means that selected peers will rather be outstanding in one of those classical disciplines than have an overall view of what "pharmaceutical science" means. If I submit a proposal for a grant or a proposal for a paper, I do not know, whether it will end being evaluated by an organic chemist, by a molecular biologist, by another life scientist or by a medical doctor. Each of these people will do his best to judge, but will judge based on the view of his own science. And this usually has little to do with required standards of pharmaceutical sciences. On the other hand, if you take Science or Nature papers, it may happen that a pharmaceutical scientist is puzzled about the low quality of the pharmaceutical aspects of published work, submitted by non-pharmacists. Such pharmaceutical work is obviously not reviewed by a pharmacist, who would sometimes have recommended not to reinvent the wheel.

Therefore, as long as we are not broadly accepted to be a scientific community of our own with its own requirements and standards, we will have a hard life to follow the criteria of molecular biologists, medical doctors or chemists, who are not really qualified to serve as peers in pharmaceutical sciences.

Best regards
Christian Noë

New Safe Medicines Faster Award
EUF EPS Award sponsored by sanofi-aventis

The New Safe Medicines Faster Award is an honour awarded every year, at a EUFEPS Congress or Conference. This Award should reward an individual scientist, or a team of scientists, for outstanding contribution to the innovation and advancement of new methodology or technology for drug development. The introduction of innovation must have happened during the ten years preceding the year in which it is presented.

The work awarded must also be original and deal with the drug development process. It may cover any aspect from basic research to applied research. It must be innovative and should provide a basis for a faster and/or more efficient drug development process and approval. It should be based on experimental or practical work. If the work has regulatory implications it is an advantage, if contact to the authorities for approval has been initiated.

To be presented in Basel, December 5-7, 2007
The award 2006 went to Professor Meindert Danhof, University of Leiden, The Netherlands for his contribution to the prediction of pharmacodynamic drug properties on basis of theoretical considerations of PK/PD observations in animal studies.

In 2003, 2004 and 2005, the awards were given for the introduction of the microdosing concept, new simulation tools and efficient compound profiling, respectively.


Call for nominations
All EUFEPS Member Societies and Individual Members are invited to nominate an individual, or a team, which is considered to be worthy of the award. There are no restrictions as to nationality, origin (industry or academic establishment) or any specialisation (pharmacist or other) of the nominees. In addition to name and full address, the nomination should include a short recommendation, clearly stating the background and rationale for nomination.

Nominations of scientist for the New Safe Medicines Award 2007 should be sent by Monday, October 15, 2007 to: Hans H. Lindén, Executive Director, EUFEPS, PO Box 1136 SE-111 81 Stockholm, Sweden.
Fax +46 8 411 3217
E-mail: secretariat@eufeps.org
EUF EPS Online; www.eufeps.org
Limits to the use of “impact factors”

Why “impact factors” cannot be used as shortcut objective measures of the quality of output from an individual researcher or a research group.

The use of an “impact factor” as an apparently objective measure of research quality by authorities as well as assessment, evaluation and grant-giving bodies is steadily increasing. This represents a misuse of the original concept, as outlined below.

What is the “Journal Impact Factor”? The Journal Impact Factor was originally introduced by Eugene Garfield as an internal tool for selection of journals for the science citation index he had developed. For a given year, a Journal’s impact factor is calculated as the total number of citations in the journal that year for articles published in the two previous years, divided by the total number of articles published in the journal in the two previous years.

\[
\text{Journal impact factor for 2006} = \frac{\text{Total citations in 2004 and 2005}}{\text{Number of articles in 2004 and 2005}}
\]

Such impact factors now represent an important competitive parameter for the individual journals. This is fair enough but inappropriate uses have appeared.

“Author Impact Factor” is a monstrosity The total of the impact factors of the journals, in which an author has published, is misused as an objective measure of the research quality of that individual researcher. The sum of the impact factors of the articles published by a research group is misused for evaluation of that group. Similarly, the added factors of articles from one discipline should not be used to compare against other disciplines. These applications of the impact factor concept are wrong and should be abandoned.

Reasons why “Author Impact Factor” cannot be employed That “Author Impact Factor” represents a misuse of the concept is apparent from the following.

The impact factor
• is an average of all articles in two years.
• Some are very much cited and others are not
• is, to a very high degree, based on journals in English
• cannot tell us anything about the quality of a specific research article in that journal
• is influenced by the number of review articles which are cited more often
• does not include books
• is looking backwards
• does not take discipline differences into consideration
• does not take publication tradition into consideration
• for some smaller disciplines, is simply lower (on average)
• is added equally to all authors of a multi-author article
• is manipulated by the Company (Thomson scientific) which registers the citations

You may add to the list, as you wish.

Manipulation of the Journal Impact Factor

It is really a problem that the assessment of public research is based on data and factors, which are exposed to manipulation by a private company. The Thomson Scientific Company regulates the impact factor by being selective in counting the number of articles published in the previous years (the denominator of the equation). This raises the question as to who should check that the factor is calculated in an objective way. Assuming this question is answered, the other drawbacks of the author impact factors still apply.

How do we then assess quality?

So if we cannot use today’s author impact factor, how can we either rectify it or find an alternative measure, which is as objective as possible. Here the discipline differences between average impact factors of journals pose a problem. So if the impact factor does not apply, what objective measure should we use?

It will surely be more sensible to measure the citations specifically to those individual articles or to papers by individuals or group of scientists. Here it is obvious that certain journals are more prestigious than others and the problem still exists as to who should rank those? Other possibilities are the new measures “Google Scholar” and “CrossRef”. The application of “usage factor” is being promoted by the United Kingdom Serials Group (www.uksg.org). Finally the “Y factor”, a combination of both the impact factor and the weighted page rank as developed by Google (www.sol.ucsc.edu/nokram/papers/journal-status.pdf) represents an option, which should be further explored, if a proxy quality measure is needed. Another measure could be number of times the articles are downloaded from the internet. The pros and cons for these newer measures need careful assessment before they are recommended for wider use.

The personal peer reviewing represents a third measure. This process is already under discussion in the Newsletter.

Ole J. Bjerrum
EUFES Past-President

1 Garfield E. The history and meaning of the journal impact factor: JAMA 2006, 295 90-93
2 The PLOS Medicine editors. The impact factor game: It is time to find a better way to access the scientific literature: PLOS Medicine 2006, 3, 707-708

Reminder of EUFEPS Conference on

Integrating Systems Approaches into Pharmaceutical Sciences

December 5-7 • 2007 • Basel • Switzerland

Why
New and unique approach, laying a foundation for future research. What is it? How to do it? Are there tools for it? Helping towards new thinking and additional progress?

Cutting-edge Presentations • Breakout Sessions • Insight Information • Integrating Discussions • Wrap-up Conclusions • Core Recommendations

Submit poster abstracts, bring your colleagues, exhibit and sponsor!

Contact Information
For current programme, registration and accommodation etc, submission deadline, exhibition and sponsorship options., consult the Conference Website at the EUFEPS Online, or contact EUFEPS Meetings & Events
PO Box 1136
SE-11181 Stockholm, Sweden
Tel +46 8 7235000. Fax +46 8 4113 217
Email conferences@eufeps.org
Online www.eufeps.org
University Membership Network: Vision and First Steps

To promote the pharmaceutical sciences in Europe, EUFEPS continues its efforts to organise the scientists into relevant networks for better communication, identification of common strengths and initiation of activities of common interest. Here, the new University Membership Network is described.

Background
When the public-private-partnership concept was introduced through the Commission’s Innovative Medicines Initiatives (IMI), it quickly became clear that, in contrast to the pharmaceutical industry, regulatory bodies and patients, any single European organisation did not represent the academic side of the pharmaceutical sciences. However, the organisation of the IMI, with its “stakeholders forum”, would benefit from an organisation of the academic side.

EUFEPs, which has been instrumental in the preparation of IMI, saw the need for a better organisation of the academic arm and looked for options. EUFEPS per se is not considered to represent academia, as we also include researchers from industry and regulatory bodies. It was an obvious idea to organise a cluster of universities linking the academic, who are already engaged in EUFEPS’ activities. This was prepared during 2006, and a group of 25 universities was invited to form such a network. The founding meeting took place on April 23, 2007, at the PSWC 2007 in Amsterdam. Since then, 3 teleconferences have been held, and the structure and organisation has evolved.

Vision
When mature, the University Membership Network will be able to act as a true node for European universities that host research in discovery, development and evaluation of medicines.

Mission
Clearly, the University Membership Network will form:
• A unique link between universities that host research in discovery, development and evaluation of medicines.
• An influential platform for future research funding of pharmaceutical sciences in Europe.
• A node for information exchange, coordination and collaboration towards European specialist training (courses) and master level programmes within the pharmaceutical field.
• Insight into long-term, ambitious, European programmes and plans related to pharmaceutical sciences, including funding application material to allow early and proactive preparation.

Furthermore, membership of the Network will give access to a EUFEPS communication platform for:
• Short announcements of courses for graduates and PhDs.
• Short announcements of professorships and similar positions.
• Short announcements of PhD positions, where financing is in place.
This communication platform is under formation.

How this Network will operate
• The Network Website is run by the EUFEPS Vienna Branch Office. It contains a Wiki, which is kept up-to-date by representatives of the member universities themselves (see below).
• EUFEPS infrastructure supports the network and its activities.
• The Network will get access to the EUFEPS’ communication platform.
• Many secretarial functions are taken care of by the Network members.
• Information relevant to the Network, which is accessible to the EUFEPS Secretariat, will be forwarded to the Network.
• Otherwise, the network is self-sustaining from its own ideas to be taken up and activities to be initiated. Positions that involve EUFEPS support and acceptance have to pass the Executive Committee.
• Network representation at EUFEPS Council is under consideration.

How to communicate
One or two contact persons at each university are liaised with the Network. The activities of the Network are brought to his/her attention by direct mailing. Otherwise, the Network Website will be used for communication. This is operated through the new EUFEPS Branch Office in Vienna: http://vienna.eufeps.org/ with access to a special Wiki website after the membership has been accepted. Thus, access is granted after the membership has been established. Regular monthly teleconferences will be held. Minutes will be issued and posted on the Website.

How to use the Network
Through input from the Network participants, topics for discussion will be taken up and opinions on the subjects sought. If agreed, a position paper will be prepared on the topic for further exposure to relevant authorities and the public. This may go hand in hand with discussions in EUFEPS’ other media, e.g. the EUFEPS NewsLetter. Topics so far discussed include:
• The IMI Joint Undertaking (JU) - how it will operate, how the calls will be generated and how will assessment be conducted.
• Education and Training course suggestions in drug development.
• Salary for teaching at e.g. IMI organised courses.
Other topics include:
• Institutional peer review systems.
• Responsibility for quality aspects by the pharmaceutical scientist and faculty.
• Postgraduate courses of excellence in pharmaceutical sciences.
• Curriculum for a European Master of Pharmaceutical Sciences.

With time, the Network will develop further activities of common interest.

Network membership
The University Network is open to application from all universities/faculties/schools/ institutions conducting research and educating PhD students in pharmaceutical sciences.

When fulfilling these criteria, the relevant information on the Website at: http://vienna.eufeps.org/uni-network/ should be filled in, as indicated.

The fee per year is set to € 1 per student in the following strata:

EUFEPs Newsletter Vol 16 No 3/07
Successful Second BBBB Conference

September 13-15 • 2007 • Tallinn-Tartu • Estonia

These pictures communicate nice environment (1), many countries represented (2), a warm welcome by Professor Peep Veski, Chair Organising Committee (3), excellent and challenging contributions, including plenary ones by Professor M. Saarma, Helsinki FI, on neurotrophic factors (4) and by Professor A.T. Florence, London UK, on new paradigms in drug research (5) in the beautiful Assembly Hall of the University of Tartu (10), delegates listening, learning and enjoying (7, 9 and 12), excellent organisation and service by Dr V. Matto (6) and his team, a thank-you for it all by the EUFEPS Executive Director, Hans H. Linden (8), an Estonian honorary recognition of Professor M. Marvola, Helsinki FI for his contributions to science, for years (11), and the geographical spread of oral and poster contributions, summarised by Professor Pia Vuorela, Helsinki FI, in two slides (13 and 14), also Chair EUFEPS Steering Committee: Meetings and Events. There are a few hundred more slides, programme and abstracts posted on the BBBB Conference Website at: www.med.ut.ee/farmaatsia/bbbb so have a look!

Why BBBB?
It represents: Balaton (Hungary), Baltic, Bled (Slovenia) and Bosporus (all by water). The first BBBB Conference was held in 2005 in/at Balaton, and the next one will be organised in October 2009, in Antalya, Turkey.

<table>
<thead>
<tr>
<th>Student Number</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;300</td>
<td>€ 300</td>
</tr>
<tr>
<td>301-600</td>
<td>€ 600</td>
</tr>
<tr>
<td>601-900</td>
<td>€ 900</td>
</tr>
<tr>
<td>&gt;900</td>
<td>€ 1200</td>
</tr>
</tbody>
</table>

Also regional clusters or associations of universities can join. The fee structure will be reevaluated in 2008.

The future
It is our hope that this new Network will evolve into a structure that is able to gather the interests of most European Pharmaceutical academic players and will be able to talk with one voice on matters of common interest in a the European context.

Universities and Institutions of the EUFEPS University Membership Network
Åbo/Turku, Finland
Bradford, United Kingdom
Copenhagen, Denmark
Ghent, Belgium
Milan, Italy
Nottingham, United Kingdom
Utrecht, the Netherlands
Vienna, Austria
Tefarco Innova, Italy (13 ones)
Top Institute Pharma, the Netherlands

Norbert Haider
EUFEPs Vienna Branch Officer
Ole J. Bjerrum
EUFEPs Immediate Past-President
C A L E N D A R

Careering towards the future: debating pharmacy education from undergraduate to...where?
November 12, 2007, London, UK
Contact: Science Programme Manager
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7 JN, UK
Fax: +44 020 75722506, Email science@rpsgb.org

Tabletting Technology
for the Pharmaceutical Industry
November 19-21, 2007, Cambridge, UK
Contact: Science Programme Manager
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7 JN, UK
Fax: +44 020 75722506, Email science@rpsgb.org

QA, QC, GXP for Pharmaceutical Production
October 5-6, 2007, Long Beach, CA, USA
Contact: Andrew B. Goryachef, Centre for Systems Biology, School of Biological Sciences
The University of Edinburgh, Edinburgh EH8 9LE, UK, Email andrew.goryachef@ed.ac.uk
www.bioinformatics.ed.ac.uk/sigsim/index.html

EuPAT 2: Scientific Progress Underpinning Process Analytical Technology
November 13-14, 2007, Copenhagen, Denmark
Contact: EUPAT Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden, Fax: +46 8 4113217
Email secretariat@eufeps.org www.eufeps.org

Integrating systems approaches into pharmaceutical sciences
December 5-7, 2007, Basel, Switzerland
Contact: EUPAT Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden, Fax: +46 8 4113217
Email secretariat@eufeps.org www.eufeps.org

SIDS Basics of Skin: Pharmaceutics and Pharmacology
December 5-7, 2007, Miami Beach, Florida, USA
Contact: Society for Investigative Dermatology
820 West Superior Avenue, 7th Floor, Cleveland Ohio 44113-1807; Fax 216 579933
Email kimble@sidnet.org or slade@sidnet.org
www.sidnet.org/SID_Basics.asp

Online www.eufeps.org

EUF EPS Events in 2008

Conférences, workshops and courses, in the pipeline, include:

Safety Issues in Optimising Biotech Medicines
March 2008, in Munich, Germany (preliminary)

Monoclonal Antibodies
April or May 2008, Heidelberg, Germany (preliminary)

When Variability Becomes an Issue: Towards understanding, prediction and management in drug development
May 2008, Verona, Italy

Quality by Design & Quality Risk Management
May 2008, London, United Kingdom

High-throughput Drug Metabolism and Disposition
May/June 2008, Amsterdam, The Netherlands

Drug Transporters
October 2008, Uppsala, Sweden

Process Analytical Technology (PAT) Sciences
October/November 2008, Gothenburg, Sweden (preliminary)

Harvesting the Molecular Biology (Revolution)
October 2008, Vienna, Austria

Optimising Drug Discovery and Development
December 2008, Basel, Switzerland

For specifics, consult the EUFEPS Online, register as Individual Member of EUFEPS, send your name and email address for the EUFEPS Flash mailing list, and/or your full address for printed circulations to:

EUF EPS Meetings & Events
PO Box 1136
SE-11181 Stockholm, Sweden
Tel: +46 8 7235000
Fax: +46 8 4113 217
Email conferences@eufeps.org

7th Central European Symposium on Pharmaceutical Technology and Biodelivery Systems
September 18-20, 2008, Ljubljana, Slovenia

Focus
New achievements in pharmaceutical technology and on the development of biodelivery systems. It will, as previous symposia in the series, offer ample time and space for scientific exchange - oral sessions and poster presentations, plus Satellite on Challenges and Opportunities in Multiparticulate Drug Delivery.

Location
Ljubljana is the capital city of Slovenia, in central Europe - in 2008 also the "Capital city of Europe", due to Slovenian European Union Presidency.

Information
For more information, access the Symposium Website at: www.cespt2008.org/ or contact:

General Secretary of the Symposium
 Assist. Prof. Dr. Sasa Baumgartner, MPharm
University of Ljubljana
Faculty of Pharmacy
Askerceva 7, 1000 Ljubljana, Slovenia
Phone: +386 1 476 96 33
Fax: +386 1 425 80 31
E-mail: sasa.baumgartner@fffa.uni-lj.si

EUF EPS Newsletter Vol. 16 No 3/07