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## Excipient GMP - where are we now in Europe?

*IPEC Europe held its first ever GMP conference in Munich earlier this month and board member Kevin McGlue updated Excipients Insight on the highlights of the event.*

The overhaul of pharmaceutical legislation by the European Commission in 2004 brought in GMP requirements for active ingredients and made the development of a Directive on GMP for excipients inevitable. But with proposals to apply GMP to 'Certain Excipients' stalled, it remains unclear what the regulatory landscape will be in Europe in the coming years.

The First European conference on GMP for Pharmaceutical Excipients, which was organised by IPEC Europe and took place in Munich earlier

this month, provided a good opportunity to hear from a distinguished panel of speakers on the current state of play.

Sabine Atzor of the Pharmaceutical Unit of DG Enterprise and Industry at the European Commission, presented some of the rationale behind the 'pharmaceutical package' which will include various elements to control counterfeiting, pharmacovigilance and other issues, but also elements that will drive through to excipient GMP in terms of the control of starting materials.

The package' - a bundle of proposed legislation, guidance and communication efforts aimed at reforming pharmaceutical regulation in the European Union - had not been published at the time of the conference, but was made public on 10 December and will be visited in more depth in a future edition of *Excipients Insight*.

A number of issues still need to be resolved before the Certain Excipients guidance can be progressed, she said. The Commission has been diverted by the need to do something about counterfeiting, and next year there will be European Parliamentary elections which are also likely to slow progress.

Katrin Nodop of the European Medicines Agency (EMA) provided an update on the position with respect to the amendment of Chapters 3 and 5 and various Annexes. Most importantly from IPEC Europe's perspective, the EMA intends next year to release a revision to Part II of its GMP guide.

"What was clear from the presentations is that there is a commitment to bringing risk-management principles into Part II of the GMP guide covering active pharmaceutical ingredients," commented McGlue.

*Continues page 3*



# The word from the chair

Dear Members,

December 18, 2008

With the holiday season upon us, the *Excipients Insight* team is getting ready to log off, and grab a festive foie gras. This being the time of year for giving (and taking), it seems only right to start by thanking our members, our committees, the IPEC Europe secretariat for their relentless efforts and contribution to the success of IPEC Europe.

With your help, a lot has been achieved in 2008: the creation of *Excipients Insight*, key for our communication and for your day to day activity, has given us a great tool to highlight some of the key achievements IPEC Europe and beyond.

Our first IPEC Europe GMP conference, held earlier this month in Munich, which is also the subject of our feature article this month was a success. We had a fantastic turnout, with more than 100 participants in total, which reflected the high standard of the programme and speakers. It was particularly gratifying to see that 40 attendees were non-IPEC members, so the event fulfilled the key objective of communicating the issue to a wider audience. We also had valuable



meetings with the Pharmaceutical Development Group (PDG) under the TriPEC banner, and agree long-term goals for the IPEC organisation.

2009 promises to build on the momentum generated in 2008, and of course the IPEC Europe Seminar and AGM will provide a great launchpad for our activities, and provide an opportunity to meet the new members who have joined us during 2008. On that subject I'm sure you will join me in welcoming our latest recruits, Abbott Laboratories and SE Tylose (see below). I invite you to take a look at the seminar programme and, with just over a month to go before the event, encourage you to book your place as soon as possible.

Thank you once again for your valuable input and support this year. I wish you a happy holiday season and look forward to welcoming you to Cannes in the New Year.

On behalf of the IPEC Europe Board,

*Patricia Rafidison*

Chair to IPEC Europe



## Member's Corner



### IPEC Board elections - final call!

We would like to remind you that three positions within the Board are open for election in 2009 (two for manufacturers and one for users). The election will be made at the next Annual General Meeting on 23 January 2009 in Cannes.

All members interested must submit their candidature by email or fax to the IPEC Europe Secretariat by **5 January, 2009**, at the latest. The vote will be organised at the Annual General Meeting on 23 January, with the new Directors taking up their positions at the following Board meeting.

For more information and/or to apply:  
Email: [info@ipec-europe.org](mailto:info@ipec-europe.org);  
Fax: +32 2 732 34 27



### GMP and GDP certification project

The excipient certification project, run with the European Fine Chemicals Group (EFCG), remains our top priority. IPEC Americas and IPEC Europe along with the Pharmaceutical Quality Group (PQG) are developing a GMP certification standard, scheme and auditor competency. GDP aspects will be covered by the GDP committee and the European Association of Chemical Distributors (FECC).

Communication of the benefits of this ambitious project is critical, so our congratulations go to Tim Boelke of EFCG for his polished video interview on certification given at CPhI in Frankfurt this year to [www.in-PharmaTechnologist.com](http://www.in-PharmaTechnologist.com).



## All systems go for the IPEC Europe Seminar and AGM



### Hotel Majestic, Cannes, 22 & 23 January 2009

The provisional programme of the 2009 IPEC Europe Seminar is now available to view [here](#), and once again promises to be a fantastic event.

Representatives of EDQM and WHO will provide an update on their objectives and strategies. Supply chain and the excipient certification project are high in the programme, but many other interesting issues will be discussed, such as needs and expectations on excipient manufacturing in relation to Quality by Design (QbD); GDP/Excipient Pedigree; and paediatric formulations in relation to excipients.

As time is marching on, we encourage you to book accommodation at your earliest convenience, as the Majestic hotel is expecting to be busy at the time of the seminar, and the Hotel Gray D'Albion has already run out of rooms.

To register please contact the IPEC Europe Secretariat at [info@ipec-europe.org](mailto:info@ipec-europe.org)

## New IPEC members

IPEC Europe is delighted to welcome two new member companies this month.



Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Its products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. For more information, contact [Dr. Paul E. Knight](#).



SE Tylose GmbH & Co. KG is one of the world-wide leading producers of cellulose ethers, and its products are used in almost all aspects of life. For more information, contact [Dr. Eckart Krämer](#).

## Excipient GMP

continued  
from page 1



"We should remember that Part II is what everyone reaches out to as a guide for starting materials, and this in turn serves as an indication that the future of GMP for excipients will also likely be based on those principles."

The revision of Chapter 5 - which includes sections on the qualification of suppliers and testing of starting materials - was in the 2008 workplan and would have affected excipients directly but has been delayed.

### FDA position

If the EMEA is to apply risk-management principles across the board for its revision of GMP, it is aligning itself with the US Food and Drug Administration's position.

Excipients are not approved by the FDA, even though they are officially defined as drug products, according to the agency's Steve Wolfgang. However, the FDA creates a cumulative listing of excipients that are used, and this database, which includes information on the excipients use. This allows it to assign a level of GMP according to risk-management principles, and make the best use of limited regulatory resources.

Some of the principles of that risk-management approach, which could provide food for thought in Europe, include:

- parenteral versus oral route;
- natural origin versus synthetic;
- lengthy supply chain; and
- whether the excipient participates directly in drug delivery.

Nodop's presentation also stimulated a lot of discussion on the topic of auditing, and once again there are some interesting clues to future directions for excipients from the way the EMEA is viewing the situation with APIs.

"The message we are getting on APIs is that paper audits play a part, but alone are not adequate," said McGlue. "There should really be an on-site audit." It is likely that a similar approach could be applied to critical excipients.

### Know your supply chain

What emerged from just about every presentation - both from regulators and industry speakers - was the need for complete and thorough knowledge of the supply chain, continued McGlue.

That in turn prompted a lot of lively discussion about the role that certification could play in supplier and supply chain qualification.

Sources of excipients are not specified in marketing authorisations but existing legislation on starting materials makes it absolutely clear that sources have to be controlled, even if it is not specified down to the level of audit.

## French excipients register: have you responded?

The French pharmaceutical trade association (LEEM) has asked IPEC Europe to remind its members of the need to comply with the excipients registry, implemented by the French health authorities (AFSSAPS) earlier this year.

Decree number 2008-109, which came into effect on 5 February, requires that manufacturers, distributors and importers of active pharmaceutical ingredients, excipients and/or any substance to be used in human or animal make a declaration of their activities.

Two types of documents need to be provided to the AFSSAPS, namely the declaration,

which needs to be submitted by 29 January 2009, and a descriptive dossier. An annual update is required only if a change in circumstance needs to be declared. Failure to declare could result in fines.

LEEM notes that pharmaceutical companies which are already registered with AFSSAPS need not submit an additional declaration.

The IPEC Europe Secretariat would like to hear from any members who have already submitted such a declaration, particularly with regard to any feedback they have received from the agency.

## News from the IPEC committees



### GMP Committee

The Committee met, jointly with the RA Committee, on 17 November at [ECCO](#) in Brussels.

The excipients certification project is taking shape and will take up a lot of time for the team in the next 12 months. Some GMP committee work will be delayed whilst that takes priority. As announced in November, all members are invited to participate and contribute to this important and demanding project. If you are interested please contact [Iain Moore](#).

Other updates this month:

- The Excipient Qualification Guide is in press for presentation and distribution at the IPEC Europe AGM in Cannes on 23 January.
- Excipient Information Package: comments by IPEC Americas are expected in early 2009. More input to adjust it to European needs have to be made.
- Dates of next meetings in 2009: 21 January (Cannes, France); 21 April (Brussels, Belgium); 20 October (Brussels, Belgium).



### Regulatory Affairs Committee

The Committee met on 17 November in Brussels at [ECCO](#)'s premises jointly with the GMP Committee.

- Residual Solvents: IPEC Europe is part of a consortium to discuss the FDA approach to the US Pharmacopeia chapter. The FDA position (see Q&A document [here](#)) seemed to require more information from excipient suppliers than ICH Q3C. However it seems that the task force had achieved its objective in defining a common position. For background information on this topic please refer to the [November issue](#) of *Excipients Insight*.

If you are interested in participating in RA Committee activities, please contact the chair, [Carl Mroz](#).



### Harmonization Committee

- The Committee is currently commenting on the European Pharmacopeia silica monographs, but also on those concerning Methylhydroxyethylcellulose, Cellulose acetate butyrate, and Hydroxyethylcellulose.
- Feedback is also expected from the PDG on further excipients to be harmonized starting in 2009. As soon as these are finalized member companies are invited to give input and to send experts to participate in the Committee discussions.

If you are interested in participating in Harmonisation Committee activities, please contact the chair, [George Mansveld](#), or the vice-chair, [Bernhard Fussnegger](#).



# Eye on Europe

## Joint CHMP/CVMP Quality Working Party Work programme 2009

According to its [2009 work programme](#), the European Medicines Agency (EMA) Quality Working Party is scheduled to have four plenary meetings, organise one workshop or training for assessors, one joint QWP/GMP Inspectors meeting, and one interested parties meeting.

The demanding work plan includes many CHMP/CVMP guidelines for revision and/or publication to contribute to, for example:

- guideline on radiopharmaceuticals;
- guideline on pharmaceutical development of medicine for paediatric use; and
- guideline on conduct of bioequivalence studies for veterinary medicinal products.

The QWP will also contribute to the development and implementation of (V)ICH guidelines. The regulatory activities include the revision of the variations regulations 1084/2003 and 1085/2003.

The QWP intends to collaborate with the European Directorate on the Quality of Medicines (EDQM) on a number of issues, including:

- project for impurities;
- development and review of pharmacopoeial monographs, general chapters and notices;
- certification of suitability scheme policies;
- sampling and testing of centrally authorised products;
- matters related to the PDG; and
- contribution to EDQM quality-related seminars.

The QWP will continue to collaborate with regulators outside the EU, and other interested parties, such as industry associations for consultation of concept papers and guidelines, and to dialogue on new technologies and approaches of common interest.

## Volume 9A implementation: questions & answers

The EMA released a [questions and answers document](#) (version 3.2) on the European Commission's [draft revision of Volume 9A](#) - guidelines on pharmacovigilance for medicinal products for human use.

It is worth noting that according to the Q&A document excipients have to be included in the EudraVigilance Medicinal Product Dictionary (EVMPD) as regards their role as ingredients for: vaccines; insulins; radioactive compounds; and immunoglobulins.

The Commission is seeking comment on the proposal by 31 January.

## EMA publishes user guide for micro, small and medium-sized enterprises (SMEs)

The European Medicines Agency (EMA) has published in October a [user guide](#) on the administrative and procedural aspects of the provisions laid down in Regulation (EC) No 726/2007 that are of particular relevance to SMEs.

The aim of the guide is to "facilitate understanding of the main aspects of medicinal product legislation," according to the EMA. The guide is structured to follow the chronological stages of developing a medicinal product.

The guide includes an overview of the scientific data requirements for obtaining a marketing authorisation in the European Union (EU). The regulatory procedures in place to optimise development and obtain an EU marketing authorisation are also summarised.



It provides information on the SMEs initiative, scientific advice, medicinal products development (both human and veterinary), applications for centralised marketing authorisation, as well as "National provisions for SMEs applicable to the pharmaceutical sector" as an appendix.

## European Commission provides update on veterinary medicinal products

At the European Commission, DG Enterprise and Industry has released a revised version of the veterinary [Volume 6B - Presentation and content of the dossier](#) concerning Part 1: Summary of the dossier - Part 1A Application form - Administrative data.

The revision contains some corrections and aims at improving the format to facilitate the practicability and usage of this template, according to the Commission.

As a reminder to our members, here is a selection of key points of interest for excipient suppliers and users in this volume:

- ▣ The Maximum Residue Limits (MRLs) according to Council Regulation (EEC) No 2377/90 of all substances contained in the veterinary medicinal product have to be provided if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in any of the Annexes of Council Regulation (EEC) No 2377/90 should also be listed and an appropriate justification given.
- ▣ The marketing authorisation application particulars include amongst others: the qualitative and quantitative composition in terms of the active substance(s) and the excipient(s) [quantity, unit, reference/monograph standard]; and the list of materials of animal origin contained or used in the manufacturing process of the veterinary medicinal product, such as active substance, reagent/culture medium, and excipient (also starting materials used in the manufacture of the active substance/excipient).

## Formulating better medicines for children

2-3 March 2009



The Royal Pharmaceutical Society of Great Britain, in partnership with the Academy of Pharmaceutical Sciences and the European Paediatric Formulation Initiative will present Formulating better medicines for children on 2-3 March 2009 at the RPSGB, London two years after the implementation of the EU regulation on medicinal products for paediatric use.

The conference - one of the first of its kind - will explore the practical challenges involved in formulating children's medicines (including the acceptability of excipients) and provide the opportunity for delegates to discuss the issues surrounding the availability of age-appropriate formulations for the benefit of young patients. The conference will bring together industrial pharmacists with an interest in children's medicines, pharmaceutical scientists involved in R&D, manufacturing, supply, delivery devices and clinical trials of paediatric dosage forms with regulators and health professionals concerned by the challenges of paediatric dosage form development.

[Click here for more information](#)



## Eye on Europe *cont'd*

### EDQM updates on harmonisation activities

At its last meeting, the European Directorate on the Quality of Medicines' Pharmacopoeial Discussion Group reported that harmonisation has been achieved on 10 of the 11 General Chapters identified by the ICH Q6A Guideline.

Evaluation of the text by ICH Q4B and the corresponding ICH Expert Working Group led to a minor revision for the general chapter on dissolution testing. A revision of the general chapter on bacterial endotoxins was approved which will allow the submission of the corresponding package to ICH Q4B for evaluation in mid-2009.

Additional items for sign-off included the excipient monograph for carmellose and a minor revision of the monograph for magnesium stearate. PDG also agreed to add lactose for inhalation to its work programme.

At last count, 26 of the 35 general chapters and 40 of the 62 excipient monographs had been harmonised, said the PDG.

The three pharmacopoeias also exchanged information on the further process of revising the heparin monographs in light of the recent safety issues associated with contaminated heparin API. They agreed to follow future activities closely with a view to ensuring "harmonised approaches."

More information is available [here](#).

### Analytical method for heparin

The Laboratory of the EDQM & Healthcare has adopted a capillary electrophoresis method developed at Utrecht University to test for the presence of oversulphated chondroitin sulphate (OSCS) in heparin samples. The method, described [here](#), can distinguish OSCS from heparin, as well as heparin from chondroitin and dermatan.

### Ph. Eur. meeting report

The European Pharmacopoeia Commission held its last meeting on 25-27 November. More information on the work programme can be found [here](#), while a report on the session's achievements - including the adoption of 23 new monographs and general chapters - is available [here](#).

### EDQM forges closer ties with Russia

The Council of Europe/EDQM, the Russian Federal Service for the Supervision of Public Health and Social Development and the CIS (Commonwealth of Independent States) Executive Committee held a conference in Moscow on 23-24 October on "Standardisation of medicines, harmonisation of requirements".

The discussion focused on quality of medicines and how to improve the cooperation, particularly on the issue of counterfeit medicines. The parties will also start preparing for the official translation of the European Pharmacopoeia into Russian. More information [here](#).

## 5th European Paediatric Formulation Initiative Meeting

The 5th European Paediatric Formulation Initiative (EuPFI) Meeting was held on 25 November in London. Kevin McGlue attended on behalf of IPEC Europe.

One of the main topics for discussion was the EuPFI comments to the European Medicines Agency concept paper on the development of a quality guideline on pharmaceutical development of medicines for paediatric use (see also *Excipients Insight* August/September edition, page 2).



EuPFI is a consortium of seven major European pharmaceutical manufacturers together with two industry associations (ACSM - the Association of Specials Manufacturers and IPEC Europe) and paediatric medicine experts; EMEA also sends an 'observer' to meetings.

The aim of the Initiative is to gather together best knowledge in the area of paediatric medicine formulation for the benefit of all.

The initiative currently has four workstreams:

- Data on excipients for paediatric formulations;
- Taste, flavouring & taste masking;
- Devices; and
- Extemporaneous preparations.

The Initiative has a number of papers in preparation for publication and members are preparing to sign off on the Consortium Agreement that in turn will facilitate the employment of a research assistant early in 2009.

One of the first tasks of the research assistant will be to gather together available data for excipient use in paediatric medicines.

Kevin will give an update on activities at the IPEC Seminar in Cannes in January.

EuPFI is holding its first major event, a two day Conference/Workshop entitled 'Formulating better medicines for children' at the Royal Pharmaceutical Society of Great Britain, London, UK, on 2-3 March 2009.

Details are available [here](#).

The next EuPFI meeting will take place on the afternoon of Tuesday 3 March, immediately after the conference.



## Events calendar

### Open discussion forum on "Revised European Guideline on Bioequivalence"

Bonn/Germany, 14-15 January 2009

The basis for this [meeting](#) is the EMEA/CHMP [draft guideline on the investigation of bioequivalence](#), released for consultation in July 2008 for comment by 31 January 2009. The intention of this event is to give scientists from industry and academia the opportunity to discuss the new regulations with representatives from regulatory authorities in Europe.

### IPEC Europe Seminar and AGM

Cannes/France, 22-23 April 2009

More information on page 2 and [here](#).

### PAT/QbD conference

London/UK, 10-11 March 2009

Informa LifeScience is organising a conference Process Analytical Technology (PAT) and Quality by Design (QbD) in 2009, and has invited IPEC Europe to participate. Further details will be provided when they become available.

### 5th Annual Global Pharmaceutical Conference - Current worldwide regulatory and compendial expectations: impact on laboratory operations

Frankfurt/Germany, 2-4 April 2009

This [conference](#) is directed toward regulatory personnel, pharmaceutical analysts, formulators, researchers and pharmaceutical manufacturers.



# Eye on the world

## News from TriPEC



### FDA awards contract for Quality by Design research

The FDA has awarded a \$1.19m contract for the development of quality by design (QbD) guidance for pharmaceutical manufacturers. Under the contract the National Institute for Pharmaceutical Technology and Education (NIPTE) will develop design specifications.

NIPTE is a nonprofit consortium of 11 pharmaceutical engineering universities. Research by the consortium will start this year and is predicted to finish in September 2010, after which the information gained will be made public.

By the end of the contract the US Food and Drug Administration (FDA) is hoping to have furthered development its QbD initiative, which aims to take a more scientific approach to pharmaceutical development and manufacture. In particular the contract is intended to enhance quality control, improve manufacturing efficiency and provide more front-end quality so the system is less reliant on back-end inspections.

This extract of a longer article is provided courtesy of [in-PharmaTechnologist.com](http://in-PharmaTechnologist.com).

### USP Expert Committee votes glycerin contaminant limits

The US Pharmacopeia's Excipients Monographs 1 Expert Committee voted on November 19 to change the limit of diethylene glycol and ethylene glycol in the Identification test of the USP glycerin monograph to 0.10% (originally proposed as 0.025%).

In the upcoming weeks, USP will post a Revision Bulletin for the revised glycerin monograph. More information is available [here](#).

### ...and redesign of USP monograph format

Meanwhile, the USP is also seeking comments on proposed design changes to all monographs contained in its United States Pharmacopeia-National Formulary (USP-NF).

As of 3 November, redesigned monographs are available on [www.usp.org/monoRedesign/](http://www.usp.org/monoRedesign/) for comment. The monographs will be posted on a staggered basis in alphabetically ordered sets.

Each set of monographs will be available for comment for 90 days. More information [here](#).

### TriPEC meeting - Brussels, 12-14 November

The recent TriPEC meeting provided fertile ground to discuss the key issues affecting excipient suppliers and users.

Compendial topics were extensively discussed prior to the meeting with PDG, as well as strategic planning and prioritisation process for TriPEC.

Third-party certification was high on the agenda. The attendees supported the working groups' initiative to hold meetings with key stakeholders to actively get their contribution and participation in developing a workable procedure.

IPEC China will officially be invited to attend TriPEC meetings from 2009. As a result of this expansion it was agreed to convene again in February-March to discuss and define the global strategy of the enlarged PEC group.

All parties agreed with the proposal that TriPEC would be renamed IPEC, with suffixes will be added to reflect regional identity for newly incorporated groups. JPEC are considering establishing IPEC Japan within JPEC; the outcome will be known at its next annual meeting in June 2009.

TriPEC's long-term goals were established and included:

- Certification standards and programme;
- Development of global standards/information and publications;
- Harmonisation of monographs;
- Service provider: education and training services to members and excipient stakeholders;
- Technical focus areas (e.g. nanotechnology, excipient safety, heavy metals, potential genotoxic impurities, counterfeiting, paediatric medicines, residual solvents, recombinant excipients, excipients derivative from GMOs, allergens); and
- Process for rapid policy development on/management of significant excipient issues on a global basis.

### PDG/TriPEC meeting - Brussels, 13 November

At the annual PDG/TriPEC meeting, the two groups updated each other on current work.

Several monographs for international harmonisation and the process of harmonisation-by-attribute as proposed by TriPEC were discussed, and comments and actions noted down to enhance the communication and the collaboration between all stakeholders. TriPEC said it would be willing to participate in any efforts to complete action items to accelerate progress on true method harmonisation.

For more information please contact the Harmonisation Committee chair [George Mansveld](#).



## IPEC China shines at China-Pharm 2008

IPEC China's first public conference took place alongside the China-Pharm 2008 exhibition and conference in Beijing last month, with more than 100 delegates in attendance.

The 2008 Excipients Supplier Chain Security International Forum, organised by IPEC China and China Center for Pharmaceutical International Exchange (CCPIE), took place on the second day of the conference.

Zhang Wei, director of the Department of Drug Registration, under SFDA, was invited to discuss the present and future of pharmaceutical excipients regulation; and an Steve Wolfgang of the



FDA introduced the excipients GMP & GDP management in the USA. Other presentations focused on IPEC America's excipient qualification guideline, supplier auditing and certification, and the implications of the rapidly-globalising market for excipient supply.

### IPEC China website now online

Meanwhile, IPEC China has also unveiled its new website - [www.ipec-china.org](http://www.ipec-china.org) where you can find more about IPEC China, benefit of membership, news, events and related links. Documents to join this association can be found [here](#).



# Excipient industry news round-up



Like to see your news featured here? Send your releases to [info@ipec-europe.org](mailto:info@ipec-europe.org).

## Is zein about to find its way out of the excipient maize?

Rising demand for maize derived biofuel may finally be making zein proteins, one of the plant's principal extracts, an economic excipient option say researchers at the UK's University of East Anglia (UEA).

Zein proteins, which are clear, tasteless, water-insoluble, edible molecules that are generally recognised as safe (GRAS), are used in the food industry for a wide variety of applications ranging from biodegradable packaging to confectionary coatings.

As yet however, zeins have not been used as an excipient in the drug sector despite their apparent suitability due to the relatively high cost of extracting the proteins from raw maize with respect to established alternatives.

Lately though the growing demand for maize derived ethanol for biofuel which produces zein as a co-product, has significantly lowered extraction costs and made the protein an economical excipient option.

Earlier this year, researchers at the UEA's School of Chemical Sciences and Pharmacy, led by Dominique Georget, published positive results from one of the first in-depth examinations of zein as a drug excipient.

This extract of a longer article is provided courtesy of [in-PharmaTechnologist.com](http://in-PharmaTechnologist.com).

## Dow foam granulation used in second B-MS candidate

News that drugmaker Bristol-Myers Squibb is using Foam Granulation Technology (FGT) to develop a second drug has worked formulation specialist Dow Wolff Cellulosics into quite a lather.

Unlike traditional liquid binders, Dow uses an excipient foam to improve particle coverage. The advantage is the greater surface area of the foam versus a liquid, which means it can be spread more rapidly and evenly over powder beds.

This extract of a longer article is provided courtesy of [in-PharmaTechnologist.com](http://in-PharmaTechnologist.com).

## Raw material contamination a hot topic at AAPS

The pharmaceutical industry's vigilance in ensuring the safety of raw materials was criticised at this year's AAPS, with significant, challenging alterations needed to improve the system.

Speaking at an AAPS Hot Topic seminar, Richard Moreton, vice president of pharmaceutical science at FinnBrit Consulting, highlighted the level of change that will be needed in the coming years.

Moreton demonstrated the current state of affairs by asking if any of the R&D workers and clinical trial suppliers in the audience knew the source of every ingredient they used; very few, if any, hands were raised.

To minimise the risk of a repeat of the glycerin and heparin scandals Moreton called on companies and regulators to initiate changes in policy and attitude. Glycerin contaminated with diethylene glycol has killed around 600 people over the last 70 years.

Relating to raw materials across the board Moreton said that non-specific assays need revising as they make it easier for fraudsters. Before changes to assays are implemented Moreton said that companies should be aware of their particular limitations, which is especially important for excipients.

In addition to changes to technologies Moreton said that education and attitudes to raw materials need to change. There has been a trend towards this with three bills currently in the US Congress, which would impact on the excipient and active pharmaceutical ingredient (API) supply chain.

Moreton also mentioned the Food, Conservation and Energy Act 2008, which if applied literally would require any plant derived material used as an excipient to have its botanical source listed on the label.

If applied to the pharma industry Moreton believes it would be a "nightmare" but went on to say that regulations far more inconvenient than those currently in place could be applied in the future.

This extract of a longer article is provided courtesy of [in-PharmaTechnologist.com](http://in-PharmaTechnologist.com).

## BASF certifies excipient range

German chemical giant BASF chose this year's AAPS meeting in Atlanta, US to showcase its growing library of USP excipient verification certificates, making good on its commitment to apply the highest manufacturing standards to this area of its business.

At present, the manufacture of excipients is not governed by same strict standards applied to both active pharmaceutical ingredients (API) and drug intermediates, largely because they are produced for a disparate range of uses across a wide variety of industries.

Recent tragedies linked to poorly made or counterfeit excipients have resulted in suggestions from some quarters, including both the USP and the International Pharmaceutical Excipients Council (IPEC) that the industry needs to be subjected to more stringent regulation.

BASF was certified following US Pharmacopeia inspection of its manufacturing facilities in Geismar, Louisiana and Ludwigshafen, Germany, becoming the third firm to sign up to the USP's voluntary program after India's Deepak Fertilizers and Petrochemicals and US-based International Specialty Products.

The certificates on display at the American Association of Pharmaceutical Scientists (AAPS) meeting cover BASF's Povidone, Crospovidone and Copovidone products, which are part of the polyvinylpyrrolidone Kollidon range that is in widespread usage across the drug industry.

This extract of a longer article is provided courtesy of [in-PharmaTechnologist.com](http://in-PharmaTechnologist.com).

## IPEC Europe

Supporting the interests of pharmaceutical excipient developers, producers, distributors and users

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