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## Pharmaceutical excipients: where now for GMP?

*Phil Taylor reports on efforts in the EU to develop a consistent set of GMP standards for excipients. Our thanks go to RAJ Pharma for permission to reproduce this article extract.*

Regulating the large and fragmented group of companies that manufacture pharmaceutical excipients for the European market is a challenge, but the present lack of a legally enforced good manufacturing practice standard is arguably the most pressing regulatory issue affecting the sector.

GMP is a legal requirement for every component of a medicine, including the active pharmaceutical ingredient and packaging materials, but excipients are currently an exception to that rule. That seems counter-intuitive when one considers these ingredients are very often the largest constituent in a medicine by weight.

The main problem is that the excipient "industry" is in fact hard to define. It is made up of hundreds of companies, selling thousands of products which often have uses outside the pharmaceutical industry, such as in food or personal care products, and so adhere to different production standards. Often the supplier may not even be aware of all the intended uses for its excipient products by its customers.

Suppliers of excipients and the pharmaceutical manufacturers that use them have worked around this hole in the regulatory fabric for years, and in most cases have relied on self-

regulation and internal auditing systems to ensure quality. From a regulatory viewpoint the responsibility is clearly on the marketing authorisation holder to ensure the quality of its medicines, and this extends to their constituent ingredients.

Many now believe that excipients should be brought into line with other constituents of medicinal products and be manufactured in accordance with appropriate GMP standards. Concerns about the risks of contamination with viruses or transmissible spongiform encephalopathies (TSE) through some excipient materials, or a repeat of incidents in Haiti, Panama and Bangladesh where substitution of the excipient glycerol by counterfeiters had lethal consequences, have provided a contextual driver to mandate GMP for excipients.

In the 2006 Panamanian case, for example, a Chinese factory was found to have exported diethylene glycol mislabelled as the glycerol suitable for use in medicines. The result was some 100 fatal poisonings.

Earlier occurrences make for similar grim reading. In 1990, cough syrup contaminated with solvents led to 47 reported deaths in Nigeria. Between 1986 and 1998 in India and Bangladesh, paracetamol

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# The word from the chair

Dear Members,

January 15, 2009

It's my great pleasure to welcome you to the first edition of *Excipients Insight* in 2009, which promises to be an eventful year for IPEC Europe and our sister organisations around the world.

Some of you will be reading this edition in a hard copy format at our annual general meeting and seminar - entitled *Excipients in focus* - in Cannes, France. To those of you at the conference - Bienvenue! Those of you who were unable to make it this time will be missed, but we hope to see you at other IPEC events later in the year. The presentations from the seminar will be available for download from our website.

Once again we are privileged to have a distinguished panel of speakers at the event including representatives from the EDQM, WHO and FDA, who will provide expert insight into the pressing issues affecting the excipient industry today.

Over the next couple of days you'll hear insightful commentary on topics such as supply chain security and excipient pedigrees; the development of harmonised standards; moves

towards quality by design (QbD); factors to consider when developing paediatric formulations of medicines and, of course, the ongoing work on the proposed excipient supplier certification programme.

The last year has seen a fantastic increase in the IPEC Europe membership and - once again - I'm delighted to report two new recruits to the cause in this monthly editorial.



We have had both an excipient user and a supplier join us in recent weeks, so please join me in extending a warm welcome to Finland's Orion Corp - represented by Antii Valimaa - and Rockwood Pigments - represented by Christian Egger. More details are given below.

Finally, all that remains is for me to wish you a happy and prosperous 2009!

On behalf of the IPEC Europe Board,

*Patricia Rafidison*

Chair to IPEC Europe



## Member's Corner



### EuPFI Consortium Agreement



As member of the European Paediatric Formulation Initiative, IPEC Europe has been asked to approve a consortium agreement that specifies that one of the main aims is "building and maintaining a database on excipients for use in paediatric medicine".

Members of the EuPFI consortium include commercial groups; academic and other associations (including IPEC Europe); and observers (such as the European Medicines Agency).

Industry members will contribute funding to the consortium, which will operate on a not-for-profit basis, over an initial period of three years. Confidentiality principles and Intellectual Property are clearly laid out in the agreement.

The Board approved this document at its meeting of 8 January 2009.



### New IPEC Members



Orion Corporation, based in Finland, develops, manufactures and markets pharmaceuticals, active pharmaceutical ingredients and diagnostic tests for global markets.

Contact person: Antii Valimaa,  
[anti.valimaa@orion.fi](mailto:anti.valimaa@orion.fi), +358-10-4261



Rockwood Pigments a primary manufacturer and processor of liquid, powder and granulated pigments and pigment-handling systems, supplying a broad range of industries including pharmaceuticals.

Contact person: Christian Egger,  
[c.egger@rpigments.com](mailto:c.egger@rpigments.com), +39-011-2280574

## Excipient GMP

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syrup contaminated with diethylene glycol resulted in 236 reported deaths, while a similar case of diethylene glycol poisoning led to 88 reported deaths in Haiti in 1996.

Low-cost competition from emerging markets as a consequence of the globalisation of pharmaceutical trade has intensified competitive pressure in a market where margins have already been squeezed by increasing commoditisation.

One driver for the move to introduce mandatory GMP in the European Union has been the growing presence of imported excipients from countries such as China and India.

There have been fears that overly stringent GMP requirements - for example at the same level as those applied to active pharmaceutical ingredients - could levy a disproportionate cost burden for excipient manufacturers whose business is largely concerned with non-pharmaceutical applications. This has even led to suggestions that some manufacturers could exit the marketplace entirely.

In Europe, the control of excipients is achieved via the directives applying to the medicines themselves and the onus is on the drug manufacturer to demonstrate the safety and suitability of the excipient. There is no direct supervision of excipients defined in law, and regulatory authorities do not tend to inspect excipient manufacturers.

In effect, a pharmaceutical company's qualified person - the individual identified as responsible for quality in the organisation - "regulates" excipients on the basis of compliance with pharmacopoeial monographs and quality control specifications. In practice, that means expectations and implementation differ in line with company philosophies and strategies.

The most plausible scenario in which an excipient supplier might be inspected would be if the regulator considered the excipient an API. However, unlike in the US, API facility inspections are not mandatory under European law.

The regulatory environment for excipients is subject to change in Europe, however, as part of the new legislation amending the existing pharmaceutical laws that was introduced in 2005

This new legislation requires API manufacture to be performed according to GMP, ie the harmonised, International Conference on Harmonization GMP standard ICH/Q7A4. Directive 2004/27/EC specifically mandated the implementation of GMP for "certain excipients" including:

- excipients prepared from materials derived from a TSE-relevant animal species, with the notable exception of lactose;

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## Excipient GMP

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- excipients derived from human/animal material with potential viral contamination risk;
- excipients claimed to be sterile (or sold as sterile) and used without further sterilisation;
- excipients with the specification or claim that they are endotoxin/pyrogen controlled; or
- specific excipients, namely propylene glycol and glycerol.

The European Commission consultation process on "certain excipients" raised concerns that the implementation costs of GMP for excipients could be greater than the patient safety benefits. Industry was keen to move towards a risk-based selection for regulation, in line with the principles laid out ICH guideline Q9, on quality risk management.

The consultation process reached a head earlier this year, when an independent impact assessment report carried out by consultants Europe Economics on behalf of the commission recommended a "no-change policy", as it concluded that the risks to patients were low.

On that basis, Europe Economics said the

preferred option should impose the lowest costs on excipient suppliers and users. Tighter regulation could make European excipient manufacturers less competitive and encourage manufacturers of pharmaceuticals to obtain supplies from outside the EU. While imported excipients should pass quality standards, if that is not the case it could lead to an overall reduction in average quality, says the report.

However, issue has been taken with some of the cost assumptions in the report. Among the predictions were that the cost of legal quality enforcement for certain excipients in Europe would come in at €26.5m per manufacturer, but that exceeds the average net sales of pharmaceutical excipients for European manufacturers by several-fold.

The impact assessment also predicts that the cost-impact of self-regulation would be €12m per manufacturer. However, there is already wide acceptance and implementation of voluntary quality guidelines, including those the GMP Guide for Pharmaceutical Excipients drawn up by IPEC Europe in association with the Pharmaceutical Quality Group in 2006.

*This extract of a much longer article is provided courtesy of Regulatory Affairs Journal Pharma. For more details on RAJ Pharma please visit their [website](#).*

## Pharmaceutical package is a 'missed opportunity'

On 10 December 2008, the European Commission published its 'pharmaceutical package' - a series of legislative reforms aimed at hiking patient safety through the development of a strengthened system of safety monitoring for patients, efforts to tackle the growing issue of counterfeit medicines, and allowing drugmakers to provide direct-to-consumer (DTC) information on their products, something that is currently banned in the EU but allowed in the US.



What was absent from the package, however, was any real progress on the development of formalised Good Manufacturing Practice (GMP) guidance for excipients.

Article 46a (formerly 46) of the package is unchanged and clearly states that GMP "shall also apply to certain excipients, the list of which as well as the specific conditions of application of which shall be established by a Directive adopted by the Commission."

So no change there, and the Commission has effectively maintained the status quo as recommended by its impact assessment published at the end of 2007. Industry will now have to handle the issues as best it can in the meantime.

### 'Uncertain' excipients?

Commenting on the development, Iain Moore, chair of IPEC Europe's GMP Committee, said: "at least we know where we are today in that nothing has changed or is proposed to change. A known uncertainty perhaps."

But the package did contain one very good idea, according to Moore, namely the requirement that third-party audit bodies - overseeing active pharmaceutical ingredient suppliers - be accredited by the national competent authority.

"This was exactly our proposal to the European Medicines Agency (EMA) at the interested parties meeting in London in November," he noted. "So in theory that idea would seem to be acceptable for excipients too."

The other headline news from the package (albeit with no direct impact on excipients) was the revelation that the European Commission has stopped short of imposing a ban on the practice of repackaging - which would have effectively ended the parallel trade in medicines. The proposals still have to be reviewed and ratified by the European Parliament and Council, a process which will likely take months.

## News from the IPEC committees

All the IPEC Europe Committees would like to meet on 21 January at the Majestic Hotel in Cannes. If you are interested in joining any of them or participate in some of their activities please contact the chairs:

- GMP C.te: [Iain Moore](#)
- Regulatory Affairs C.te: [Carl Mroz](#)
- Harmonization C.te: [George Mansveld](#), or the vice-chair [Bernhard Fussnegger](#)
- GDP C.te: [Allan Whiston](#).



### GMP Committee

The key agenda items to note include:

- ▣ A discussion on the impact of the EC pharmaceutical package published in December;
- ▣ Quality agreement template for excipient manufacturers: the document has been issued for QA proof reading;
- ▣ Certification project: project plan in place with team leaders assigned for the 4 main components: classification; GMP; GDP; Auditor Competency. Those members of the certification teams who are present will meet after the GMP/RA meeting to further develop their ideas.



### Regulatory Affairs Committee

Some of the main items for discussion at the committee meeting will include:

- ▣ Composition Guide: comments were sent to IPEC Americas for review before publication.
- ▣ Quality by Design: members to consider taking this topic on board as part of the RA agenda or as a separate committee.



## EMA unveils concept paper on revision of guideline on parametric release

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has published a [concept paper](#) for the revision of the [note for guidance on parametric release](#) (CPMP/QWP/3015/99).

The document explains the EMA's reasons for revising the guidance. In particular, it says the current note was developed before the publication of the ICH guidelines Q8 Pharmaceutical Development, Q9 Risk Management and Q10 Pharmaceutical Quality Systems.

As specified *"Even if it is clearly stated in the current guideline that the concepts in it can be applied to any stage of manufacture, detailed information is only given on application of parametric release to sterility. [...] A revision of the Guideline on Parametric Release will bring it in line with the ICH Q8, Q9 and Q10 documents and clarify to what extent Q8, Q9 and Q10 should be followed when an applicant wishes to introduce replacement of end product testing by other approaches."*

*"By elaborating more on examples from process stages other than sterilisation, the revised guideline will also encourage companies to take advantage of these new developments in the area of pharmaceutical development and manufacture."*

Comments to this concept paper can be provided to the EMA/QWP at [QWP@emea.europa.eu](mailto:QWP@emea.europa.eu) by February 2009.

## Guideline on radiopharmaceuticals

As announced in December, the EMA/QWP has approved and now published the final [guideline on radiopharmaceuticals](#) for coming into effect in May 2009.

"This guideline describes the specific additional information that needs to be submitted in relation to radiopharmaceuticals, in the context of applications for marketing authorisations or variations to authorised medicinal products."

The section related to the drug product specifies that the "influence of radioactivity on the excipients should be discussed".

Control of excipients should be done based on the Note for Guidance on Excipients in the dossier for application for marketing authorisation of a medicinal product (CHMP/QWP/396951/06).



## Clarification on the acceptability of CEP applications for sterile material

The European Directorate on the Quality of Medicines has published a [document](#) to clarify the conditions for acceptability of applications for certificate of suitability (CEP) to the monographs of the European Pharmacopoeia materials for which the sub-title sterile is requested.

It says: *"an application for a sterile grade material can only be accepted if the sterilisation step is considered an integral part of manufacture of the material as performed by the manufacturer."*

*Certificates, which have already been issued for sterile grade material where this requirement is not met will continue to be valid, if maintained up to date by the certificate holder. Any new application which does not satisfy this requirement that the sterilisation operation is an integral part of manufacture carried out by the manufacturer will not be accepted."*

## Quality project

The EDQM also announced that "after having set up its quality management system, the EDQM is continuing its actions in this area and has started to carry out the work needed to request ISO 9001 certification.

The first activity to go through the certification route will be the procedure for Certification of Suitability to the Monographs of the European Pharmacopoeia (CEP). The certification audit is planned for the end of 2009."

## Communication empowers the public to participate in minimising health risks

The EDQM has developed a new model for risk communications strategies for drug regulatory authorities, the scope of which is to prepare and implement risk communication procedures at national level, to proactively raise awareness and share specific information about incidences so helping to minimise possible harm. Such an approach would also be a step forward in the fight against counterfeit medicines. More info [here](#).

## Pharmeuropa 21.1 - January 2009

The list of contents of the new Pharmeuropa 21.1 edition is freely available on the EDQM website [here](#).

We invite you to have a look at it and to provide EDQM with your comments if any. The draft monographs and general texts can be commented on by 31 March 2009.



## DG Competition - Pharmaceutical Sector Inquiry - Preliminary Report

The European Commission Directorate General on Competition has published a [preliminary report](#) of a pharmaceutical sector inquiry.

The document focuses on a number of issues, including competition between originator companies and generic companies; competition between originator companies; and the regulatory framework, in particular rules on patents, marketing authorisations, and on pricing/reimbursement.

The annex to this document provides an overview of claim types found in pharmaceutical patents: it includes 'formulations' as comprising *"more than just the active ingredient, and typically contain other compounds, often referred to as pharmaceutical excipients."*

*"These excipients can have a profound effect on the behaviour of the active agent, often assisting in its delivery to the body. Protection for these products is therefore also of great concern to pharmaceutical companies since it is usually the formulations themselves which are marketed."*

## EC bags major haul of counterfeit medicines

The European Commission's [Medi-Fake](#) operation, which targeted customs control on illegal medicines, has given an alarming insight into the scale of counterfeit medicines imports into the EU.



László Kovács, the EC Commissioner for Taxation and Customs, said: *"in a two month period, Customs seized more than 34 million illegal pills, far exceeding expectations."*

On the basis of a risk profile disseminated by the Commission, customs from the 27 member states put special focus over a two-month period on coordinated action to stop illegal medicines from entering the EU. Among the products which were intercepted were the inevitable erectile dysfunction drugs, but also antibiotics, anticancer drugs, antimalarials and cholesterol lowerers, painkillers and drug precursors.

That provides further evidence that counterfeiters are targeting life-saving as well as so-called lifestyle drugs, and also highlights the risk of fake or substandard raw materials ending up in medicines made by pharmaceutical companies.



# Eye on the world



## FDA Draft Guidance on Genotoxic Impurities

In December 2008, the US Center for Drug Evaluation and Research, CDER, published draft guidance for Industry, 'Genotoxic and Carcinogenic Impurities in Drug Substances and Products'.

The document is intended to inform industry of FDA's current thinking on the topic and has some similarities with the EMEA Guideline (EMEA/CHMP/QWP/253144/2006 effective 1 Jan 2007) in that the recommendations are not to be applied retrospectively, unless there is a specific cause for concern. However the CDER document includes in the scope additional recommendations for dealing with potentially genotoxic impurities during clinical trials, whereas the EMEA guidance applies to marketed products.

The CDER and EMEA are in line in thinking that in general, an exposure level of 1.5µg of impurity per person per day is an acceptable qualification threshold level to support a marketing application and no further safety qualification need occur.

The CDER also discusses the options of setting specifications for impurities on calculated permitted daily exposure levels where adequate evidence for a threshold mechanism exists.

### \*\* Late News - Good Importer Practices \*\*

As this edition of *Excipients Insight* went to press, the FDA unveiled a draft guidance document on Good Importer Practices. More details and analysis in a future edition, but in the meantime the document can be downloaded [here](#).

### New FDA Commissioner named

Frank Torti will become acting Commissioner at the FDA when the current incumbent, Andrew von Eschenbach, steps down.

Torti joined the agency in April last year taking the newly formed post of chief scientist, details of which can be found here. Currently there is no decision on when a permanent appointment will be made or who will take the post.

### Agency opens up in Latin America

The FDA has established its first permanent presence in Latin America with the opening of an office in Costa Rica. More offices are scheduled to be set up in the region over the next 12 months, with Mexico and an unnamed South American country next in line.



## Public International Conference on Harmonization meeting

As announced in the October *Excipients Insight*, a public ICH regional meeting was held in November to inform on recent developments at ICH level and to raise questions on quality, safety, standards development and efficacy topics (see agenda).

**Presentations** of particular interest concerned: the new ICH Regulators Forum; the Revision of Guidance on Genotoxicity Testing & Data Interpretation for Pharmaceuticals intended for human use (ICH S2 (R1)); Implementation of Q8, Q9 and Q10; as well as a discussion of pharmacopoeial harmonisation by Michael Wierer (EDQM and Pharmaceutical Development Group). In [this presentation](#) he analysed the latest PDG achievements on excipients and general chapters, and said that the priority is to work on dosage-form general chapters and excipients.

### Workshop on Implementation of ICH Q8/Q9/Q10 and other quality guidelines

A workshop on the implementation of ICH quality guidelines was held in Beijing, China, from 3 to 5 December 2008. There were over 200 people there which included many officials from SFDA and officials from every provincial SFDA office in China along with a number of people from industry. It was a major ICH education conference.

There were many questions about excipients and significant interest in David Schoneker's presentation on Excipient Variability and its Impact on QbD, from both Chinese regulators as well as a number of the speakers from FDA, Health Canada, MHLW and Europe.



### US Pharmacopeia

The US Pharmacopeia (USP) has entered into an agreement with the UK National Biological Standards Board, which manages the National Institute for Biological Standards and Control (NIBSC), to improve the quality of medicines. By working together the two bodies are hoping to improve and harmonise biologics quality standards. In particular they will be developing reference materials and entering into collaborative research arrangement.

# News from TriPEC



## TriPEC Strategic Planning Meeting

In February 2009 a TriPEC meeting will be held in Los Angeles (US) with the aim to discuss the work sharing in the future, in particular with a view to the recently formed IPEC China; as well as the need for a global education process. Priorities, including the certification project, and joint documents to be published will be revised.

## SFDA Excipient Master File group

The Chinese regulatory authority, the State Food and Drug Administration (SFDA), has set up a group to study the Excipient Master File system which met for the first time at the end of November. IPEC China said it is willing to be involved in the project.

## Audio interview with IPEC China chairman

Since its inauguration last year, IPEC China has been working to improve the quality of excipient manufacturing in the country.



In an audio interview with [in-PharmaTechnologist.com](#), spoke with the organisation's chairman, Nevin Cheng, about the steps the body has taken so far and what it will be

doing in 2009, including its plans for a new SFDA-approved Excipient Master File (EMF) scheme.

## IPEC Europe

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

IPEC Europe  
9, Avenue des Gaulois  
B-1040 Brussels  
Belgium

Tel: +32 2 736 53 54  
Fax: +32 2 732 34 27  
Email: [info@ipec-europe.org](mailto:info@ipec-europe.org)

Editor: Phil Taylor

Tel: +44 1527 835 437  
Email: [pjtcomms@online.rednet.co.uk](mailto:pjtcomms@online.rednet.co.uk)

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## Events Calendar



- ▣ **IPEC Europe Seminar and AGM**  
Cannes/France, 22-23 January 2009  
More information [here](#).
- ▣ **EMEA EFPIA Info Day 2009**  
London/UK, 24 February  
For more information, view the [agenda](#) and [registration form](#)
- ▣ **Formulating better medicines for children**  
London/UK, 2-3 March  
More information [here](#).
- ▣ **PAT/QbD conference**  
London/UK, 10-11 March
- ▣ **5th Annual Global Pharmaceutical Conference - Current worldwide regulatory and compendial expectations: impact on laboratory operations**  
Frankfurt/Germany, 2-4 April 2009  
More information [here](#).
- ▣ **Expofarma Interphex 2009**  
Mexico City / Mexico, 22-24 April  
More information [here](#).
- ▣ **IPEA GMP Auditing Workshop**  
Prague/Czech Republic, 27-29 April  
More information [here](#).
- ▣ **PharmSciFair**  
Nice/France, 8-12 June  
More information [here](#).

IPEC Europe will hold two half-day sessions, one on 11 June entitled *Excipients: the impact of emerging regulatory paradigms on excipient quality and security. Regulations for excipient manufacture and distribution practices: updates and trends*; and a second on 12 June entitled *Excipients: a vehicle for innovation through material science*.



## Science and Technology

IPEC Europe presents a digest of technical articles published in the scientific and trade press

### Understanding Excipient Interfaces

An article in Contract Pharma, authored by Andrew Parker, provides a thought-provoking review of the various testing methods - such as X-ray diffraction and Near Infrared (NIR) spectroscopy - that can be employed to explore the functionality of excipients in medicinal products.

The article discusses the key drivers for understanding excipients, outlines functionality-related testing criteria and critically discusses the merits of whether it is appropriate to list functionality-related testing in a monograph-type listing.

The entire article is available to read online [here](#).

### A Fresh Coat: Innovation in Excipients

Pharmaceutical Technology's Maribel Rios has written a feature looking at how sophisticated excipients development, especially for coatings, is staying on top of new challenges and meeting expanding pharmaceutical industry needs. The article is available to read online [here](#).

### New excipient reviewed

Pharmaceutical Technology also features an article on a new excipient - developed by BASF - that is comprised of mannitol, polyvinyl acetate, and crospovidone and can be used to create orally disintegrating tablets. The article is available to read online [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).

### Friesland Foods and Campina merge

Friesland Foods - an IPEC Europe member - has merged with Campina following approval of the deal by the European Commission.

The merger was first aired in December 2007, with the companies saying it would significantly strengthen their positions in both consumer products in Europe, Asia and Africa, and in ingredients on a worldwide basis.

As of January 1 2009 the organisation has been operating under the new name of FrieslandCampina.

The divisions involved in pharmaceuticals are FrieslandCampina DOMO (whey and milk based products for infant, medical, cell nutrition and pharmaceutical applications) and DMV Fonterra Excipients (a 50 per cent joint venture with Fonterra in pharmaceutical excipients).

### Night time release pill gains EU approval

Nitec has received approval in Europe for arthritis drug Lodotra, the first to use SkyePharma's drug delivery technology Geoclock.

Geoclock ensures that the active ingredient, prednisone, is released four hours after the tablet has been ingested. Consequently if a patient took a tablet prior to going to sleep at 10pm prednisone release would start at 2am and reach maximum plasma levels at 4am.

Geoclock encases the active ingredient in an outer tablet layer consisting of a mixture of hydrophobic wax and brittle material. This layer is not degraded by the changes in pH in the digestive system and releases the drug after a set period of time.

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

### Consortium formed to improve QbD software

Blue Reference has formed a Quality by Design Product Development Consortium (QbD PDC) to provide a forum for the improvement of its process analytics software.

The software uses raw data and evaluates process interdependencies and their impact on quality to give users an understanding of areas of the system that can be improved.

Cle Reference said in a statement that the findings of the largest empirical study ever performed on the interplay of pharmaceutical manufacturing and the FDA found that by postponing implementation of QbD practices, the pharmaceutical industry is wasting more than \$50 billion a year in manufacturing costs.

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