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Insight to Excipact™ - Excipient Certification Scheme

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ABSTRACT

The **EXCiPACT ™** scheme would introduce an independent Certification of manufacturers and Suppliers of excipients as a means of ensuring patient safety, improving assurance of Supplier quality, while minimizing the overall supply chain costs. The EXCiPACT ™ Project Global Steering Committee had set the principles and deliverables for the various project teams which would lead to "International" acceptance, anywhere in the world, "Inclusivity" for all excipients' quality standard, "Accessibility" to & from approved 3rd Party Audit organizations providing certification, "Evolution not revolution" by adapting existing best practices, guides and standards and overall "Simplicity" of the Scheme. In a nutshell, EXCiPACT ™ is an independent nonprofit legal entity, registered in Brussels, designed to help enhance patient safety and supplier quality as well as minimizing overall supply chain costs by way of sharing information about QMS.

Keywords: IPEC, EXCiPACT™, cGMP, GDP, EMA, FDA.

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INTRODUCTION

The research, formulation development, and approval of a drug product is a continuous but lengthy process involving several designs, laboratory developments, animal studies, clinical trials, regulatory registration and marketing authorization. This lengthy process is necessary to assure the effectiveness and safety of the drug product. Furthermore, to assure the quality of medicines produced, risks in the supply chain need to be evaluated and minimized. In the United States, however, no regulations were put forth until the Pure Food and Drug Act was passed by Congress in 1906. In 1931, the United States Food and Drug Administration (FDA) were formed.

The provisions of the FDA are intended to ensure that:

1. Food is safe and wholesome,
2. Drugs, biological products, and medical devices are safe and effective,
3. Cosmetics are unadulterated,
4. The use of radiological products does not result in unnecessary exposure to radiation, and
5. All of these products are honestly and informatively labeled

The safety concern led to the passage of the Federal Food, Drug and Cosmetic Act (FD and C Act) in 1938. The FDandC Act extended its coverage to cosmetics and therapeutic devices. In 1962, the Amendments to the Franc Act established an efficacy requirement for new drugs for the first time. In 1984, Congress passed the Price competition and Patent Term Restoration Act to provide for increased patent protection to compensate for patent life lost during the approval process. Based on this act, the FDA was authorized to approve generic drugs through the evaluation of bioequivalence on healthy male subjects. In addition, the FDA also has the authority to designate prescription drugs or over-the-counter (OTC) drugs.

In addition to active pharmaceutical ingredients, excipients are present and used in the formulation of pharmaceutical finished dosage forms. They serve many purposes in dosage forms, from aiding in the manufacture of the pharmaceutical product to influencing the bioavailability of the active ingredient. On average 80% to 90% of the volume of each drug product are excipients. Few of them are manufactured only for pharmaceutical use; most are destined for usage in the food or cosmetic industry. They represent a market value accounting for almost 0.5% of the total pharmaceutical market according to industry experts. The humble excipients that go into the formulation of a drug product rarely capture the attention commanded by APIs, but are critical and essential components of drugs. Some excipients help to transport the API to the targeted site in the body where it is supposed to exert its activity, protecting API molecule so it can exert the optimal therapeutic effect. Others make sure the API is released at the right time or place, thereby avoiding potential side effects. Some help to identify a product if its authenticity is in question, while others aid patient compliance by improving the taste or appearance and elegance of a medicine.

Clearly, that makes it important that they are of good and consistent quality, as even minor deviations in an excipient can have a significant impact on its pharmaceutical functionality and performance. Patients rightly expect that any medicine they take, has been manufactured to the highest standards and, while this is true most of the time, recent manufacturing problems affecting even the largest drug-manufacturers are of evidence that this is not necessarily assured. Moreover, there have been several cases in recent years where serious adverse reactions have been attributed to the excipients used in a drug product.

Several deaths of children due to side effects including disorientation and kidney failure have been reported with a case history of deliberate substitution of the widely-used excipient glycerin with diethylene glycol. [1] Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), reported that 84 children died in 2008 after being administered Barewa Pharmaceuticals' My Pikin Paracetamol-based teething syrup before it was later withdrawn from the market. Several other children who received the product subsequently suffered adverse reactions including fever, convulsions, diarrhoea, and kidney failure. An incident in Panama in 2006 saw 21 people die after taking a cough syrup made with DEG that had been mislabeled as glycerin, a widely-used excipient. A similar case involving DEG in cough syrup in 1996 led to the deaths of 88 people in Haiti, while in 1990-1992 paracetamol syrup in which DEG was substituted for propylene glycol caused 236 deaths in India and Bangladesh.[2]. There are plenty of such examples of EMA (Economically Motivated Adulteration), a phrase defined by the US Food and Drug Administration as the "fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e. for economic gain."[3] Likewise the case involving contamination of the active pharmaceutical ingredient heparin in 2008 led to dozens of deaths around the world. In this case, a toxic adulterant was added to heparin in order to boost its apparent activity. [4]

GMP FOR EXCIPIENTS

Ensuring that the excipients used in formulated drug products are of appropriate quality is the responsibility of the drug products manufacturer under the law. Whereas the supply, distribution and use of active ingredients are regulated internationally, no such schemes exist for excipients. Nevertheless, excipient suppliers, distributors and the pharmaceutical industry are committed to use quality raw materials throughout the supply chain and control this by self regulation. However, the increasingly complex supply chains in the pharmaceutical industry caused by globalization in raw materials sourcing illustrate the difficulties faced by companies sourcing excipients and other raw materials. In the Panama case above, the glycerin/diethylene glycol passed from a supplier in China not registered to supply pharmaceutical grade products through the hands of several companies and traders before being bought by the pharmaceutical manufacturer.

The European Commission has been looking at remedying this situation for several years. In 2005 it published a series of amendments to Directive 2001/83/EC on medicinal products for human use to mandate the development of a Good Manufacturing Practice (GMP)

system for excipients in order to bring them into line with other constituents of medicinal products. Against this background, experts from IPEC Europe and IPEC Americas together with partner associations from PQG (The Pharmaceutical Quality Group), EFCG (European Fine Chemicals Group) and FECC (European Association of Chemical Distributors) have elaborated quality standards for Good Manufacturing Practices and Good Distribution Practices.[5] All parties are in agreement that an international pharmaceutical excipient good manufacturing practice (GMP) and good distribution practice (GDP) certification scheme will ensure the safety of these key ingredients of drug products throughout the supply chain.
To fulfill these principles, the project had been set-up by an international group of organizations broadly representing excipient manufacturers, distributors and users.

The Project steering committee had been in the process of consulting & getting feedback from the stakeholders such as national regulators and trade associations, throughout the duration of the project.

The Key deliverables of the Scheme are concerned with:
• Classification system for excipients in relation to patient risk
• Revision of the established IPEC-PQG GMP Guide to cover manufacturing of excipients for enhanced risk classes
• GMP and GDP standards of excipients adoptable & suitable for 3rd party auditing
• Auditor competency schemes
• Certification scheme rules for 3rd party audit organizations
• Publication, communication and ongoing maintenance of the schemes, standards and guides development – a continuous up gradation process.

Overall there are more than 1,200 excipients in use in medicinal products – excluding colours and flavours – however only about 300-400 have monographs in a recognized pharmacopoeia. A significant barrier to developing effective legislation has been the diffuse nature of the excipient market and the lack of a defined excipient industry, with players in the sector spanning commodity food ingredient manufacturers through to companies that specialize in functional ingredients for pharmaceuticals. Fears have been voiced that overly stringent GMP requirements could levy a disproportionate cost burden for excipient suppliers which only provide a small proportion of their overall output to the pharmaceutical industry. It has also been suggested that the cost of compliance for these companies could rise to unbearable levels, so they may choose to stop supplying their products to the industry at all and lead to shortages.

Meanwhile other standards such as ISO 9001, widely used in other industries such as food, do not go far enough in their present form, so pharmaceutical manufacturers and excipient suppliers alike have been forced to rely on self-regulatory measures such as auditing, quality agreements and other business approaches to help ensure excipient quality. After reviewing an Impact Assessment report on the proposed directive on GMP for excipients – the European Commission planned to develop an alternative GMP strategy for excipients based on the reform of existing legal requirements on manufacturing and quality control.

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EXCiPACT™ SCHEME

Faced once again with a regulatory vacuum, industry groups such as IPEC Europe, the European Fine Chemicals Group (EFCG) and European Association of Chemical Distributors (FECC) have taken matters into their own hands to develop a universally applicable scheme based on appropriate levels of not only GMP but also Good Distribution Practice (GDP). The aim is not only to help ensure medicine quality, but also to alleviate the burden of regulatory inspections and audits on manufacturers, excipient suppliers and regulatory authorities. The system – called EXCiPACT – is based on the concept of third party certification of suppliers to a consistent and well-thought-out set of standards covering not only GMP but also other important elements GDP.

The overall aim is to develop GMP and GDP principles for excipients as an annex to the widely-used ISO 9001 Quality System, allowing excipient manufacturer and distributor companies to include certification as part of their ISO 9001 registration audits. Critically, the idea is to develop a network of third-party auditing companies, who will certify excipients suppliers and distributors to the EXCiPACT standards, taking that task out of the hands of the pharmaceutical manufacturer or indeed the regulatory authorities, who are already struggling to meet the inspection demands of drug products and APIs, let alone excipients. If the audit is successful and accreditation is awarded, the drug maker can then purchase excipients from that supplier with a degree of assurance that the firm was providing quality materials.

The EXCiPACT partners held a public stakeholder review of the standard manual and aimed to launch the certification scheme by the January 2012. As progress with EXCiPACT continues, however, the legislative situation has been continued to evolve, primarily as a result of the European Directive on Falsified Medicinal Products, which was published by the European Commission on July 1, 2011.

The final version has taken the approach even further, with the requirement that the authorities define how to classify excipients based on their potential risks to the patient. From this analysis the excipient user can then judge if the GMP applied in the manufacture of the excipient is suitable for their application. In this regard it seems to have been acknowledged that one size does not fit all when it comes to excipients. Tragically though, the European authorities have done nothing concerning the distribution of excipients and it will remain up to industry led initiatives like the IPEC Good Distribution Practices Guide to fill this particular vacuum on a voluntary basis. IPEC Europe believes that a certification scheme such as EXCiPACT has the ability to contribute to safer medicinal products by setting minimum manufacturing standards, and minimum distribution standards which can be independently verified – this will raise standards across the industry, but without creating unmanageable administrative bottlenecks. If the three main players on the stage – excipient suppliers, pharmaceutical manufacturers and regulators – can work together to develop and agree a practical and useful approach to GMP for excipients, it can only serve to enhance patient safety. The selection, including qualification and approval of supplies is an important operation which should involve staff who have a particular and thorough knowledge of the suppliers and the associated risks

involved in that starting material's supply chain. Suppliers of certain excipients considered to be high risk materials used as starting materials, should be periodically audited to confirm that they comply with current GMP requirements and that supply chain traceability of the starting material is being maintained. The findings from each audit should be documented, and audit reports should be available for review by Inspectors.

The standards of ISO norms and GMP/GDP Guidelines in the consolidated EXCiPACT document perfectly complement each other. In this way, excipient manufacturers can be assessed to both ISO and EXCiPACT™ GMP criteria. The same also applies to the assessment of excipient suppliers and distribution facilities in accordance with ISO and EXCiPACT™ GDP.

EXCiPACT is an independent, non-profit legal entity, registered in Brussels. Since 2008, it has been developed as a project via a consortium of industry experts from the European Fine Chemical Group (EFCG), the European Association of Chemical Distributors (FECC), the International Pharmaceutical Excipients Council (IPEC) Europe, IPEC-Americas, and the UK Pharmaceutical Quality Group (PQG) [6].

The mission is for EXCiPACT to become the preferred global organization that supports certification for pharmaceutical excipient manufacturers, suppliers and distributors. The vision is for the scheme to be a voluntary, self-regulated initiative of the global pharmaceutical excipient manufacturing, distributing and pre-formulating industry, supported by excipient users.

It is a scheme that:

- ensures cGMP and GDP requirements are applied to pharma excipients through a recognized auditing and certification process, thereby increasing safety and reliability as well as transparency of the supply chain
- has, as a key part of this process, the approval by a panel of experts independent of the audit, which assures the certification meets the expectation of users and the regulators
- is accepted by all major stakeholders, including relevant authorities globally
- is an independent organization able to objectively set cGMP and cGDP standards
- provides certification as a cost-efficient method of ensuring cGMP and cGDP are applied throughout the pharmaceutical supply chain by reducing the audit burden.

The four key objectives developed by the EXCiPACT project team at the outset were:

- cGMP and cGDP standards for pharma excipient manufacture and distribution that are suitable for third party auditing
- definition of third party auditor competency
- definition of training requirements for third party auditors
- establishment of certification scheme rules for third party audit organizations resulting in an EXCiPACT certificate for pharmaceutical excipient manufacturers (cGMP) and distributors (cGDP)

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EXCiPACT is initially targeting both the European and North American markets with other interested countries to follow as soon as possible afterwards. It is hoped that the scheme will provide for a safe, reliable, transparent pharmaceutical supply chain and cost savings by reducing the audit burden for both customer and supplier without sacrificing quality.

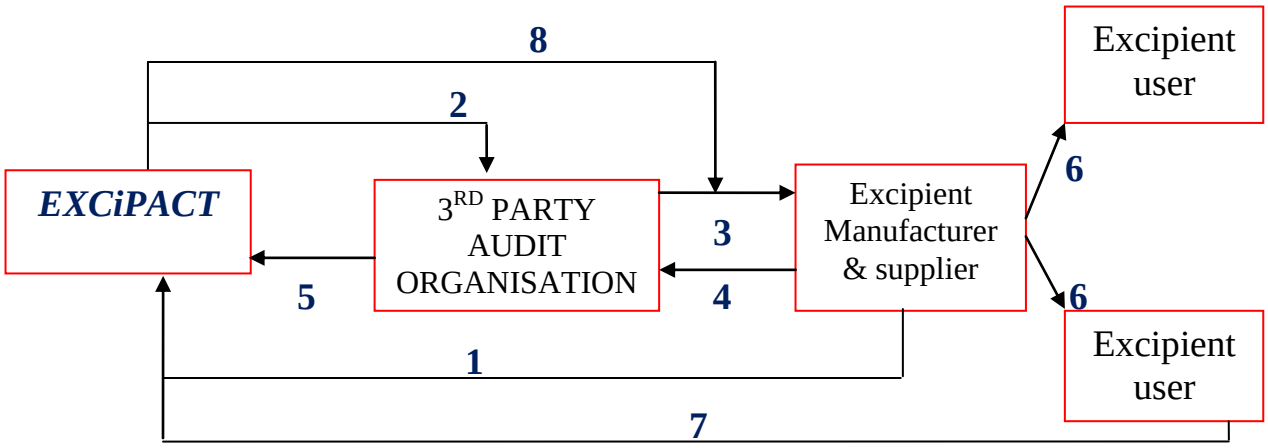
The scheme will offer the following products:

- Approval/qualification of third party audit companies issuing the EXCiPACT certificate
- Excipient GMP Annex to ISO 9001 and/or ANSI standard
- Excipient GMD Annex to ISO 9001 and/or ANSI standard
- Requirements for auditor competency and third party audit organizations providing certification

It will also offer the following services:

- Oversight of pharmaceutical excipient manufacture and distribution certification
- Auditor competency development and qualification
- Website with certification status

EXCIPACT™ CERTIFICATION, PROCESS & RELATIONSHIP:



1. Supplier Selects approved 3rd Party Audit Organization
2. EXCiPACT issues registration number to 3rd Party Audit Organization
3. Audit needs to be performed and a Certificate will be issued
4. Supplier pays audit fee (including certification fee) to 3rd party certification body
5. 3rd party Audit Organization pays certification fee to EXCiPACT and informs about audit findings.
6. Supplier provides audit results to excipient user and upon request audit documentation
7. Excipient user can verify the audit documentation with EXCiPACT
8. EXCiPACT reserves rights to attend audit or to analyze audit report in order to warrant standards.

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APPLICATION FOR EXCiPACT™ CERTIFICATION

According to this scheme, a pharmaceutical excipient supplier is certified upon completion of a satisfactory audit and a positive certification decision from a qualified 3rd party audit organization, which is assessed and judged as competent by an accreditation body and which is approved and licensed by EXCiPACT™. The EXCiPACT™ scheme (Annex to ISO 17021:2006 Conformity assessment – Requirements for bodies providing certification of excipient management systems) stipulates detailed requirements that a 3rd party audit organization shall meet in order to gain approval. In addition, the auditors employed by the 3rd party audit organization shall meet the EXCiPACT™ Auditor competency standards (Annex to ISO 19011:2002). As a minimum, the 3rd party audit organization shall be accredited in accordance with the requirements and regulations of the EXCiPACT™ certification standard, ISO/IEC 17021 and ISO 19011. The EXCiPACT™ GMP and GDP standards are annexes to ISO 9001:2008 and it is particularly effective to have a simultaneous audit against ISO 9001 and the selected EXCiPACT™ standards.

The Certification Process

It is advisable that every supplier is assessed against the current version of the standard [http://www.excipact.org]. The supplier identifies if GMP and or GDP parts are needed and a preliminary self assessment shall be conducted by the supplier against the requirements and guidance of the standard. Any areas of nonconformities shall be addressed by the supplier. Once the self-assessment has been completed and nonconformities addressed, the supplier selects a 3rdparty audit organization (ideally the one that already provides them with ISO 9001 certification). EXCiPACT™ cannot advise on the selection of a specific 3rd party audit organization, but the supplier can find EXCiPACT™ approved certification bodies on the website: http://www.excipact.org.

CONTRACT WITH 3RD PARTY AUDIT ORGANIZATION

A contractual agreement shall exist between the supplier and the 3rd party audit organization to ensure that adequate and accurate information is given to enable the 3rd party audit organization to select (an) auditor(s) with the required skills to undertake the audit. The 3rd party audit organization shall require an official application process by submission of an official application form, signed by a duly authorized representative of the supplier.

AUDIT SCHEME AND FOLLOW-UPS

There shall be a Two-Stage Initial Audit (pre-audit, full audit, Corrective and Preventive Action (CAPA), Certification) along with at least annual surveillance audits and triennial re-certification – a frequency likely to be higher than any pharmaceutical company could manage, even for high risk excipients. The duration of audits shall be adjusted according to the scope and complexity of the GMP / GDP system and excipients produced. Costs (financial and time) would be comparable to an overall ISO 9001 certification with a certification fee payable to

EXCiPACT™ through the 3rd party audit organization [which is currently €5,500 for a three year period]. If the supplier is applying for certification according to ISO 9001 he could simply extend the audit to the EXCiPACT™ certification. The supplier shall provide the 3rd party audit organization with appropriate information to allow them to review the application and to assess the duration and the costs of the audit. There is a requirement on the supplier to plan carefully for the audit, to have appropriate documentation for the auditor to assess and to have appropriate staff available at all times during the on-site audit. The initial certification is carried out at the premises of the supplier and is conducted in two stages. In the first stage the documentation of the quality management system is evaluated. An important objective of this audit is to assess the preparedness of the supplier for the audit. Any areas of concern that could be classified as nonconformity shall be resolved before the stage 2 audit. In the stage 2 audits, the implementation and effectiveness of the quality management system (QMS) is evaluated through documental as well as physical evidences. Alternatively, suppliers who do not hold ISO 9001 certification will be able to obtain an equivalent certificate through the forthcoming US national standard (ANSI-NSF 363), which also uses the EXCiPACT™ GMP standard. All suppliers will, therefore, have the choice of which certification route to follow. In either case, the requirements will be the same.

CONDITIONS FOR ISSUANCE OF CERTIFICATION

The Audit Report compiles observations and findings as life threatening, critical, major or minor non conformities. 3rd Party Technical Experts review audit report and findings, recommend certification, if there are no life threatening, critical, no major without CAPA, and no minors NCs that indicate failure of quality system element. The audit team may point out nonconformities (NCs), wherever applicable, the effectiveness of the corrections and CAPA need to be taken or committed by the supplier. On the basis of this audit report and any other relevant information (e.g. comments of the supplier on the audit report), the 3rd party audit organization shall make a certification decision. A certificate shall only be granted, typically within 30 calendar days after the 3rd party audit organization has reviewed, accepted and verified the effectiveness of the corrections and CAPA plans for the revealed nonconformities. The Audit Report – available to the pharmaceutical customer from the excipient supplier – may be redacted to show that confidential information has been hidden – but the substance of report will not be altered.

If any life-threatening nonconformity is identified, then the 3rd party audit organization will recommend the supplier to contact their customers and the relevant authorities immediately to alert them of the potential risks to patient safety and to keep them promptly informed with further communications. Should no evidence of such communications be seen then the 3rd party audit organization will notify EXCiPACT™ and EXCiPACT™ will also notify the supplier that immediate action is required, otherwise EXCiPACT™ will have to advise the relevant authorities of the risk to patient safety. Whilst the certificate is issued to the supplier, it remains the property of the 3rd party audit organization which controls its ownership, use and display. The supplier has the right to appeal the certification decision made by the 3rd party audit organization in accordance with the documented appeal handling process of the 3rd party

audit organization. EXCiPACT™ will publish a list of the certifications granted, suspended and withdrawn on their homepage.

CHANGES & SCOPE OF EXTENSION OF CERTIFICATION

Once certification has been granted, any changes that may affect the fulfillment of the requirements for the certification shall immediately be communicated to the 3rd party audit organization. This may be changes in the products or manufacturing processes that may require extension of the scope of the certification, in the management and ownership of the supplier, the location etc. The 3rd party audit organization will then conduct a site visit to examine the consequences and determine any audit activities necessary and to decide whether or not an extension may be granted. If an extension is granted the current certificate will be superseded by a new certificate using the same expiry dates as detailed in the original certificate.

FOLLOW UP SURVEILLANCE AUDITS

The certificate expires three years after the date of issuance. In the intermediate period, surveillance audits shall be conducted at least once a year. These audits shall address all schemes & follow up requirements including evaluation of internal audits and management review, review of actions taken on nonconformities identified in the previous audit, treatment of complaints, effectiveness of QMS, progress on continual improvement, operational control, review of changes and use of marks and references to certification. In case nonconformity is identified by the audit team, the 3rd party audit organization shall take a decision for continuation, suspension or withdrawal of the certificate depending on the corrections and corrective actions of the supplier.

RECERTIFICATION AUDIT EVERY 3 YEARS

Before the date of expiration of the certificate, a recertification audit shall be conducted. The purpose of this audit is to confirm the continued conformity and effectiveness of the quality management system as a whole. The fulfillment of all requirements is evaluated. The audit also includes a review of the system over the whole period of certification, including previous surveillance audit reports. Identified nonconformities are dealt with as described in the surveillance audits. The 3rd party audit organization makes a decision on renewing of the certification on the basis of the recertification audit, the review of the system over the whole period and complaints received from users of the certification.

COMMUNICATION WITH CERTIFICATION BODIES

In the event that the supplier becomes aware of legal proceedings with respect to product safety or legality, or in the event of a product recall, the supplier shall immediately make the 3rd party audit organization aware of the situation. The 3rd party audit organization in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take any appropriate action.

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CURRENT STATUS OF EXCIPACT™

The recent reported incidence of contamination of gelatin capsules [5.8% were found to contain excessive levels of chromium, according to the China's State Food and Drug Administration (SFDA)] from China emphasizes once again the necessity for IPEC to work on standards and improvement in the global supply chain of pharmaceutical excipients. Feedback from regulatory authorities in Europe has been extremely positive with The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM - Germany) and The Medicines and Healthcare products Regulatory Agency (MHRA-UK) both indicating that they see third-party schemes set up like EXCiPACT™ as key to solve the audit problem and contributing to safer medicinal products in Europe. EXCiPACT™ had reached a critical point; the standards were in the process of being finalised, and proofing of the EXCiPACT™ document being carried out with a view to publication. The EXCiPACT™ cGMP and GDP standards were made available for public and stakeholder review earlier this year. All submitted comments have been reviewed and amendments made allowing the standards waiting to be published. A pilot study using these standards to assess excipient suppliers will follow to validate the scheme. As the standards act as Annexes to ISO 9001, 19011 and 17021, organizations already ISO certified will find it very effective to extend their certifications to the EXCiPACT™ standards. Alternatively, suppliers who do not hold ISO 9001 certification will be able to obtain an equivalent certificate through the forthcoming US national standard (ANSI-NSF 363), which also uses the EXCiPACT™ cGMP standard.

Progress has been made on the implementation of EXCiPACT™. The legal agreement has been fully updated and sent to the initial certifying bodies. Meanwhile, the committee has also defined the criteria needed for the selection and approval of other certifying bodies which are scheduled to be released soon. Several new certifying bodies have been in contact with IPEC to provide EXCiPACT Certification to their existing ISO 9001 clients. Recently a discussion meeting was hosted by the PQG in London and attended by over 70 participants. There were many questions on how EXCiPACT would work, and how the audits could be assured as having high quality and integrity. However feedback was positive including from the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

EXCiPACT™ Auditor Training Courses have been planned to be organized by The International Pharmaceutical Excipients Council Europe (IPEC) for excipient suppliers looking to implement and be certified to EXCiPACT™ cGMP and or GDP Standards. Equally excipient users should also attend, especially those involved in supplier qualification because your excipient suppliers will be offering you EXCiPACT™ Certificates (and audit reports) in future when you ask to audit them. This is the ideal course to identify what the GMP and GDP standards are all about and how they will be audited.

All suppliers will, therefore, have the choice of which certification route to follow. In either case, the requirements will be the same. Legal agreements are also being drawn up with third-party auditing operations and the first auditor training sessions are in the pipeline. In conclusion, EXCiPACT™ offers the pharmaceutical supply chain the opportunity to access a

new, independent international pharmaceutical excipient cGMP and cGDP certification scheme to help set minimum standards, qualify suppliers, minimise overall supply chain costs and thereby enhance patient safety.

CONCLUSION

On 1st February 2012, the IPEC Federation has launched its new, voluntary international certification scheme, designed and developed to assure cGMP and GDP standards are being used in the manufacture and supply of pharmaceutical excipients, named EXCiPACT. Speakers from the Regulators (FDA, MHRA), and from the Industry (BASF, Croda, Pfizer, SGS and Merck Millipore) discussed in detail the reasons for creating EXCiPACT and the benefits it can bring to supply chain security, cost saving and patient safety during their meeting in Barcelona on 25th January. Much emphasis has been placed on the training and certification of 3rd party auditors to deliver the scheme. This international pharmaceutical excipient GMP and GDP certification scheme aims on providing manufacturers, suppliers and users of excipients with additional confidence that suppliers of these critical components of drug products are safe to use and, therefore, minimize patients risk. A new website for direct access to the EXCiPACT Standards is available: www.excipact.org. [7-10].

The Quality & Regulatory Affairs Committee met at the Secretariat offices in Brussels, Belgium. Among the topics on the agenda was the ongoing development of the Certificate of Analysis Guide, a final version of which has now been prepared and submitted to the IPEC Europe board for approval. The draft is available in the members' area of the IPEC Europe website.

REFERENCES

[1] www.ipec-europe.org
[2] http://www.securingpharma.com
[3] Placing excipients at the heart of safe medicines, Iain Moore and Flavia Arc; European Industrial Pharmacy; 11, Dec 2011
[4] www.pharmalot.com/2011/06
[5] www.fda.gov
[6] www.ipec-europe.org/UPLOADS/ EXCiPACT_Version_2.pdf
[7] http://efcg.cefic.org/downloads/excipients_stakeholder_meeting_PR_090621.pdf
[8] http://www.excipact.org
[9] http://www.gmp-publishing.com
[10] www.manufacturingchemist.com