Current and new issues concerning global markets and the quality of medicines: How to face the challenges and opportunities of globalization – Europe

Pharmaceutical Excipients and the Future

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What are excipients?

Excipients are components of medicines:

- Excipients have no therapeutic activity
- Excipients help formulate active pharmaceutical ingredients into finished drug dosage forms
- Thousands of different excipients used all dosage forms
- Excipients can influence the potency and bioavailability of an active ingredient

IPEC Europe

- IPEC Europe, the International Pharmaceutical Excipients Council Europe, is an association which serves the interests of producers, distributors and users of pharmaceutical excipients.
- Together with its sister associations IPEC Americas, IPEC Japan and IPEC China. It is a member of IPEC Federation whose global membership extends to more than 200 companies.
- IPEC Europe represents the views of its members to appropriate regulatory bodies and aims to be recognized by government agencies around the world as the voice of European producers, distributors and users of pharmaceutical excipients.
- For this it develops position papers and it contributes to global harmonization efforts in the fields of regulations, regulatory standards and pharmacopoeial monographs for excipients.

Dialogue

Supplier

User

Common language

IPEC Europe: main activities

To contribute to regulations, providing guidance and interpretation to ensure:

- ✓ excipients do not compromise patient safety
- ✓ their sources of supply are secured
- ✓ the unique nature of excipients is recognised through the inter-relationships between our areas of focus

IPEC Europe: our focus

- Harmonisation of monographs
- Harmonisation of standards
  - ✓Good Manufacturing Practices
  - ✓Good Distribution Practices
  - ✓Excipient Information Packages
  - ✓Quality Agreements
- Quality by Design
- Protection of intellectual property

IPEC Europe: regulation

Voice proactively that excipients must be adequately regulated but recognising that relevant criteria are not the same as for drug products/APIs:

- GMP for certain excipients
- Harmonisation of monographs
- Composition/impurities
- Emerging guidelines, for example potential genotoxic impurities and heavy metal catalyst residues
- Stakeholder relationships

IPEC Europe strategy: supply

Proactive promotion of good business practices which mitigate supply chain risks

- Counterfeiting and illegal supply of medicines still proliferate
- Recent events continue to emphasize the need for legitimate and responsible business practices
- Excipient manufacturing and distribution networks cross various industry sectors
- Work collaboratively with our sister organisations (IPEC Federation) and regulators (*GMP* (EC), *GDP* (WHO) by influencing the “What’s” and providing the “How to’s” (GMP and GDP guides and audit guides)

IPEC Europe strategy: innovation

Enable innovation and protection of proprietary information

- Promote and encourage the creation of the Excipient drug master files scheme in EU
- Facilitate more rapid adoption of monographs for new excipients

IPEC Europe strategy: the future

- **Need *regulation*:** balanced legislation to permit self regulation
- **Need *harmonisation*:** immediate globalisation and simplification
- **Need *recognition*:** excipient sources and uses must be ensured
- **Need *innovation*:** development and use of new excipients must be stimulated
- **Need *supply chain control*:** sources must be secure
- **Need *Stakeholders cooperation*:** access and partnership must be possible

IPEC Europe

one of our key commitments ....

Excipact

Project commenced in May 2008 with EFCG and IPEC Europe, now comprises 5 trade associations

- EFCG - European Fine Chemicals Group
- FECC – European Association of Chemical Distributors
- IPEC-Americas
- IPEC Europe
- PQG - Pharmaceutical Quality Group (UK)

Excipact

Motivation

- Safety of medicines for patients – recent tragedies
- Drug producers have to qualify their suppliers
  - Traditionally by a mixture of paper and physical audits
  - Now a regulatory expectation of physical audits on ALL suppliers – no current alternative to physical audits
- = Armies of auditors and auditees
  - A familiar story?
- Transparent certification schemes for all components of a drug benefit the entire industry including patients

Excipact

Why Certification?

- Absence of regulations for excipients
- Certification Scheme for self regulation
- Ability for supplier to initiate process
- Applicability to manufacturers and distributors of excipients
- Well developed and accepted assessment model

Excipact

Certification & 3rd Party Audits

- Provides information on Supplier's GMP practices from experienced auditors with knowledge of excipient manufacturing & GMPs
- Allow companies to focus resources on excipients with highest risk
- Reduces audit load for suppliers and users
- Can allow a level playing field for all
- Help smaller companies (both users and suppliers) and those with limited budgets
- Makes 100% audit verification of suppliers practical

Excipact

Goals

- Acceptance by all stakeholders
- International: certificates accepted globally
- Inclusive: applicable to as many excipients as possible
- Certification assessable for as many accredited 3rd party organizations as possible
- Evolutionary: builds on existing guides and standards
- Simple: easy to understand and apply for all stakeholders

Minimize Risks – Maximize Benefits

Excipact

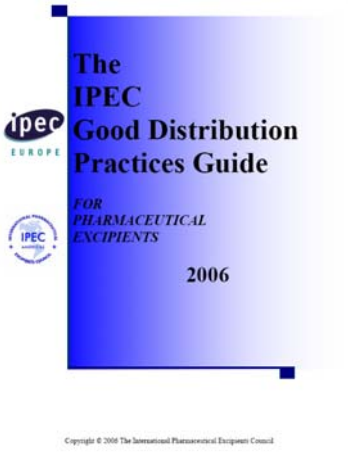
Excipient GMP focus on both Safety (as food) and Consistent quality (as API)

- Specifications, Process Capability (validation for Excipient), and Change Control with customer notification form the basis of difference between food and excipient GMP
- Starting point of full GMPs, degree of documentation & oversight form the basis of difference between API and excipient GMP
- Raw materials for excipient manufacturing are consumed by the process as compared to ingredients (excipients) for drug products that are consumed by the patient
- Failure of an excipient may result in rejection of a drug batch or decrease in effectiveness or stability of a drug product

Excipact

Good Distribution Practices

- Annex to ISO 9001 containing specific requirements for GDP – Certificate as Annex to ISO 9001 – same model as EFfCI
- Suitable for excipient suppliers (e.g. distributors)
- Allowance for different distributor/trader operations (trading, warehousing, re-packaging, bulk transport etc.)
- Harmonised requirements with IPEC GDP Guide for Pharmaceutical Excipients
- In-line with SQAS ESAD Section F&G
- Where there is overlap, GMP- and GDP-Annexes contain same requirements



Excipact

Quality of auditors is critical

- Competency framework defined using ISO 19011
- Alternative starting routes to qualification possible i.e. experienced in ISO 9001, GMP or GDP
- Considered best practices e.g. SQA and Qualified Person assessment processes
- Training Guide included
- Training programme for auditors to be developed

Excipact

Certification Scheme

Website

- List of Third Party Certification Providers
- Directory of certified excipients suppliers
- List of certifications suspended and withdrawn
- Program Procedures
  - Appeals
  - Complaints
  - Requirements of Third Party Certification Provides
  - Study Guide for Excipient GMP Certification Auditors

Excipact

Certification Scheme

Participation

- Legal Agreement between Excipact and 3rd Party Assessment Body
- Confirmation of certification held by 3rd party assessment body
- Confirmation of auditor competency and qualifications to the requirements of the scheme

Delivery of Scheme

- Target is 2011

The International Pharmaceutical Excipients Council Europe

"Helping To Shape The Future Of Excipients"

Thank you for your attention!

Beam Suffolk
IPEC Europe Chair