EXCiPACT: taking an idea to global reality

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EXCiPACT – What is it?

- EXCiPACT is a credible, independent, voluntary, third party certification scheme for manufacturers, suppliers and distributors of pharmaceutical excipients worldwide
- Managed by EXCiPACT asbl, a non-profit organisation registered in Brussels
- Quality of excipients needs to be assured throughout manufacturing and distribution
- EXCiPACT allows suppliers to prove they have adopted best manufacturing (GMP) and distribution (GDP) practices to ensure the safety of these key pharmaceutical ingredients
- Launched in Europe in 2012 and the USA in 2013.

EXCiPACT – Why was it needed?

- ✓ Safety and efficacy of medicines is paramount to all
- ✓ To assure the quality of medicines, risks in the supply chain need to be evaluated and minimised
- ✓ Risks relate to APIs and excipients
- ✓ Regulators expect pharma producers to secure their supply chain.
- ✓ New legislation in EU and US requires GMP or GDP for excipients
- ✓ Large number of on-site GMP/GDP audits needed = increased cost burden
- ✓ Regulators willing to accept demonstrably credible third party certification schemes, like EXCiPACT, to reduce the audit burden.

Agenda: Taking an Idea to Global Reality

- *Idea generation, collaboration, product definition (2008)*
- *Product development (2008-2011)*
- *EXCiPACT name, logo published and trademarks sought globally (2010)*
- *Business Plan approved (2011)*
- *Product launched in Europe and USA (2012-2013)*
- *First Certificates and Audit Reports available (2013)*
- *EXCiPACT asbl registered as a non-profit organisation (2014)*
- *Global business development (2013 - date)*
- *The Future*

Idea Generation and Product Concept: 2008

- Project initiated in early 2008 when the European Fine Chemicals Group (EFCG) identified pharmaceutical excipient quality as a problem and proposed a GMP certification scheme for excipients
- IPEC Europe, IPEC Americas and PQG shared this view and could see the numbers of audits required and expected would only increase
- A meeting was held in May 2008 from which the pharma excipient GMP and GDP Certification project was born
- Counterfeit and supply chain issues (e.g. glycerine, melamine and heparin) clearly indicated that GDP also had to be included and so FECC also joined the development team.

Idea sharing, collaboration, product definition: 2008

- Realisation: a group of willing industry people capable of developing a credible, GMP/GDP certification scheme for pharma excipients building on the collective experience of past efforts.
  - ✓ EFCG – European Fine Chemicals Group
  - ✓ IPEC Europe
  - ✓ IPEC-Americas
  - ✓ PQG
  - ✓ FECC – distributors (joined soon after)

- These industry associations and their members agreed to collaborate to deliver a GMP/GDP Certification Scheme for pharma excipients at minimal cost.

- IPEC Europe accepted the product development leadership role within the global IPEC Federation

Product Development: Considerations: 2008

- No official definition of GMP/GDP for manufacture of excipients in EU
- Regulatory Authorities have no resources to audit excipients suppliers
- Suppliers overloaded with audits yet users would like to do more
- Politicians demanding authorities provide more assurance over the quality of pharma starting materials especially GDP aspects
- Well-developed infrastructure for third party accreditation globally (ISO 9001, ISO 14001)
- Third party accreditation bodies have the infrastructure reach and resources to service large numbers of suppliers
- EC consultation in 2007 demonstrated good awareness of GMP and most respondents had a QMS in place, with ISO 9001 most common.

Project Development Teams: 2008-2011

Project Management

1. Executive
2. Global Steering Committee

Project teams

1. Certification Scheme
2. GMP Annex to ISO 9001
3. GDP Annex to ISO 9001
4. Auditor Competency annex to ISO 19011
5. Third Party Audit Organisation annex to ISO 17021
6. Business Planning

Members drawn from:

- ✓ EFCG
- ✓ FECC
- ✓ IPEC Europe
- ✓ IPEC Americas
- ✓ PQG
- ✓ Consultants

Working together as project teams under IPEC Federation as the legal entity

Project Teams: Organisations & others involvement 2008-2011

48 people from 30 Excipient manufacturers, distributors, consultants and users/pharma companies volunteered to serve on the project.

Arrow
Ashland
BASF
Bayer
Biersterfeld
BMS
Colorcon
Consultants (4)
Croda
DFE Pharma
Dow
Dow Corning
Eli Lilly
Evonik
FECC
GSK
Hedinger
Huber
IPEA
Merck
Pfizer
PQ Silicas
Roche
Roquette
Sanofi
Solvay
VWR

EU (17)
USA (9)
Consultants (4)

See Standards Booklet 2012 for further details

Product Development 2008: Key principles

Key principles adopted by all Project Teams

- ***International:*** certification should have same acceptance and value anywhere in the world
- ***Inclusivity:*** scheme should provide quality standards and be applicable to as many excipients as possible
- ***Accessibility:*** scheme should be accessible to as many third party organisations as possible
- ***Evolution not revolution:*** existing best practices, guides and standards should be utilised and adapted wherever possible
- ***Simplicity:*** overall scheme should be as simple as possible.

Product Development 2008: Key Deliverables

Key deliverables

- GMP and GDP standards suitable for third party auditing
- Definition of auditor competency for delivery of the scheme
- Certification rules for third party audit organisations
- Publication, communication and on-going maintenance of the scheme's standards and guides developed.

EXCiPACT Standards development

- Concept was to take the IPEC-PQG GMP Guide and IPEC GDP Guide and convert these to auditable standards and to use reputable third party audit organisations to perform the audits

- As many excipient suppliers were already certified to ISO 9001:2008 then converting the guides to Annexes to ISO 9001 would make adoption and assessment much simpler for both suppliers and auditors

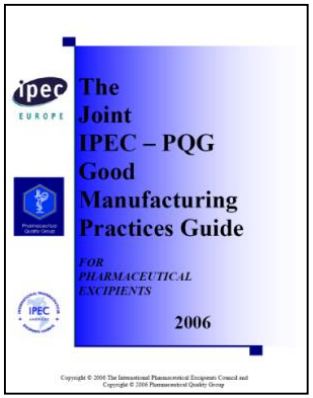
- Other Industry certification schemes already follow this model so simpler for third party audit organisations too

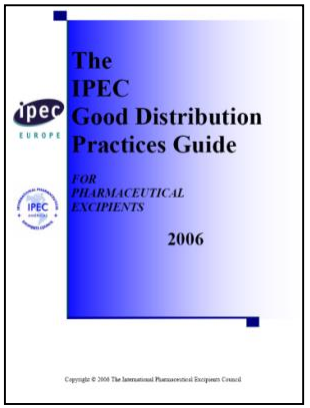
EXCiPACT Standards development

- The IPEC-PQG GMP and IPEC GDP Guides are *guidance*, their main purpose is instructional - to give ideas on "*how to do*" GMP and GDP.

- Audits against guides are possible, but too much judgment would lie with the auditor who has to decide "*what is appropriate*"

- So Guides converted to "*what to do*" standards to remove reliance on auditors having to decide "*appropriate*"





Product Development 2011: Certification Scheme Team Output

The four Scheme Components delivered by the team were:

1. Requirements for GMP for Pharmaceutical Excipients as an annex to ISO 9001:2008

2. Requirements for GDP for Pharmaceutical Excipients as an annex to ISO 9001:2008

3. Requirements for Auditor Qualification & Auditing of Excipient Suppliers as an annex to ISO 19011:2002

4. Conformity Assessment Requirements for Certification Bodies as an annex to ISO 17021:2006.

Made available on-line and as a 96 page pocket-sized booklet

EXCiPACT Business Plan: 2011

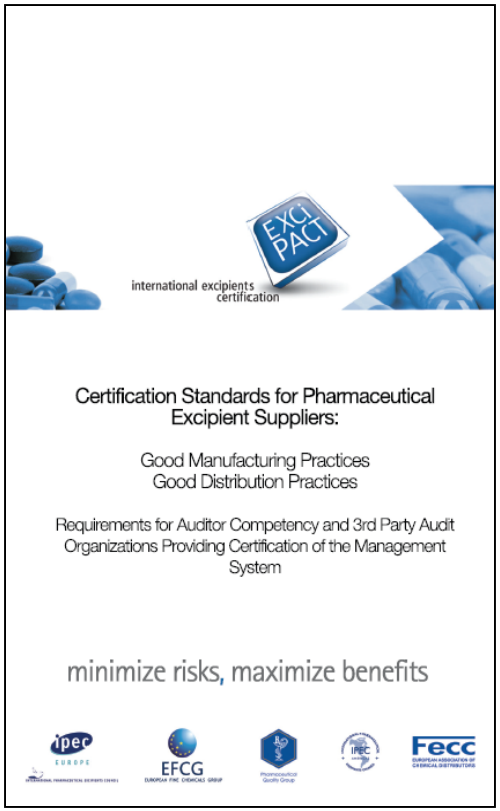
- **Ownership:** IPEC Federation 2008 - 2013. (EXCiPACT asbl from 2014)
- **Management:** Members → Board → Operations & Quality Management → Secretariat
- **Goals & Objectives:** preferred global organisation supporting independent GMP/GDP certification of pharma excipient suppliers
- **Product:** independent third party GMP/GDP Certification Scheme
- **Target Market:** pharma excipient suppliers certified to ISO 9001
- **Income:** fees from Certification Bodies and their clients
- **Competitors:** other demonstrably credible independent certification scheme suppliers

Product Testing & Launch: 2011-2012

- During 2011, the Certification Scheme and its components were rigorously tested by the Certification Scheme Team
- Outcome: Scheme approved by the EXCiPACT Board for launch
- Launch: Barcelona January 2012; Washington DC April 2013
- Attendees:
  - ✓ Excipient manufacturers/distributors
  - ✓ Pharma companies
  - ✓ Certification Bodies
  - ✓ Auditors
  - ✓ Regulators (MHRA and FDA)

EXCiPACT 2012 launch

- Standards Booklet
- Website: (www.excipact.org)



Certification Body Registration: 2013+

After product launch, formal applications were received from four Certification Bodies. EXCiPACT experts then sought to…

- ✓ Qualify them based on the '*Conformity Assessment Requirements for Certification Bodies*' set out in the standard
- ✓ Train and qualify their auditors based on the '*Requirements for Auditor Qualification & Auditing Excipients Suppliers*' set out in the standard

In 2013, three CBs met the above requirements and were approved as Registered EXCiPACT Certification Bodies after each had an auditor successfully witnessed during an EXCiPACT audit by an EXCiPACT assessor.

Third-Party Certification Bodies
EXCiPACT oversight

- 2013: SGS, Blue, DQS
- 2015: BV China
- 2016: AENOR, AJA
- 2017: Certiquality

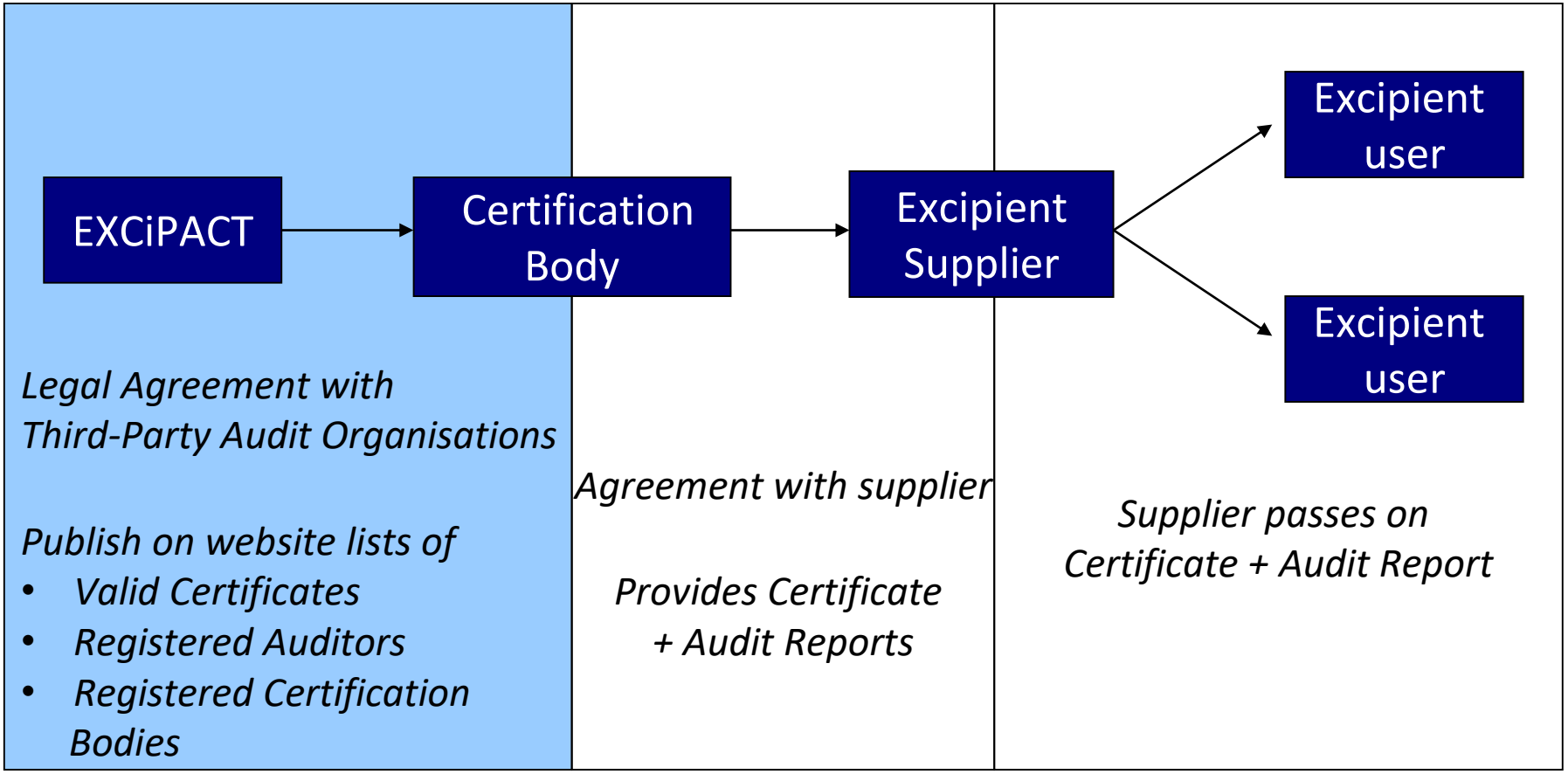
- Re-certification every three years

- For details of Registered Certification Bodies and Registered Auditors see www.excipact.org

EXCiPACT: Oversight of Certification Bodies

- EXCiPACT asbl fulfills the role of an *Accreditation Body*
- Carries out Certification Body approval via a structured process
- Ensures the Certification Body complies with all the requirements
  - ✓ Certification Body quality system definition and qualification process
  - ✓ Auditor competency definition, training course, exam, and registration processes
  - ✓ Certificate and Audit report format requirements
- All Certification Bodies are re-audited every 3 years and their performance reviewed prior to re-approval.

The EXCiPACT Certification Scheme 2011 Process and Relationships



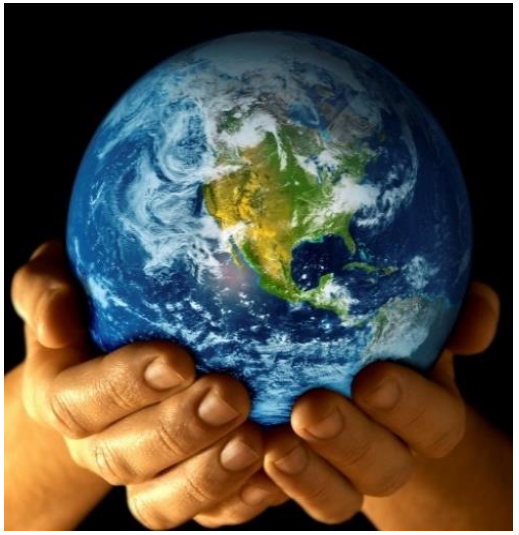
Global Business Development: 2013 – 2018

Year	Auditors	Certificates
2013	6	5
2014	6	13
2015	9	25
2016	16	43
2017	21	67
2018	23	83

EXCiPACT Global Coverage

83 Certificates have been issued in 16 countries

- ✓ Belgium
- ✓ Canada
- ✓ China
- ✓ France
- ✓ Germany
- ✓ India
- ✓ Israel
- ✓ Italy
- ✓ Japan
- ✓ Netherlands
- ✓ Saudi Arabia
- ✓ Singapore
- ✓ Spain
- ✓ Switzerland
- ✓ UK
- ✓ USA



The Future

- ✓ Revised version of the standard was issued in 2017 aligning to ISO9001:2015
- ✓ Continued marketing to secure growth in China, Europe, India and the USA
- ✓ Aiming for 200 certifications by 2021
- ✓ Lower cost scheme for ‘closed pack distributor’ GDP only certification to be launched in 2019
- ✓ Examining ways of extending our Certification Scheme to other parts of the pharma supply chain

EXCiPACT asbl is a not-for profit organization established in Belgium, with the following full members:

The Pharmaceutical Quality Group

IPEC AMERICAS

ipec EUROPE

Fecc EUROPEAN ASSOCIATION OF CHEMICAL DISTRIBUTORS

IPEC CHINA

As an association of associations, impartiality is assured.

For further information visit: www.excipact.org