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# EXCiPACT 最新发展和情况更新

EXCiPACT 研讨会  
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# EXCiPACT的发展历史

- EXCiPACT认证体系于2012年推出，并于2013年在IPEC联盟内部开始运作

The EXCiPACT Certification Scheme was launched in 2012 and became operational in 2013 within the IPEC Federation.

- EXCiPACT asbl 于2014年1月在比利时注册，成为独立存续的非盈利组织，目前有包括IPEC在内的5家会员

EXCiPACT asbl became an independent, non-profit organization legally registered Belgium in January 2014 now with 5 members including IPEC China to provide oversight of the **Scheme**



The Pharmaceutical Quality Group



- 只有协会才能成为正式会员：保证公正性  
Full Members can only be associations: so impartiality is assured

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# EXCiPACT 认证体系

## What is it?

**It is an independent, voluntary, 3<sup>rd</sup> party certification scheme for pharmaceutical excipient suppliers (manufacturers and/or distributors)**

- Developed between 2008 – 2011 by suppliers and users of pharmaceutical excipients
- Comprises:
  - GMP & GDP Standards for pharma excipients - as annexes to ISO 9001:2008
  - Certifying Body quality system definition and qualification process - as annex to ISO 17021:2006
  - Auditor competency definition, training course, exam, and registration process - as an annex to ISO 19011:2002
- Launched Jan 2012 via a 96pp pocket-sized booklet
- Update to be published in late 2017 based on new ISO standards

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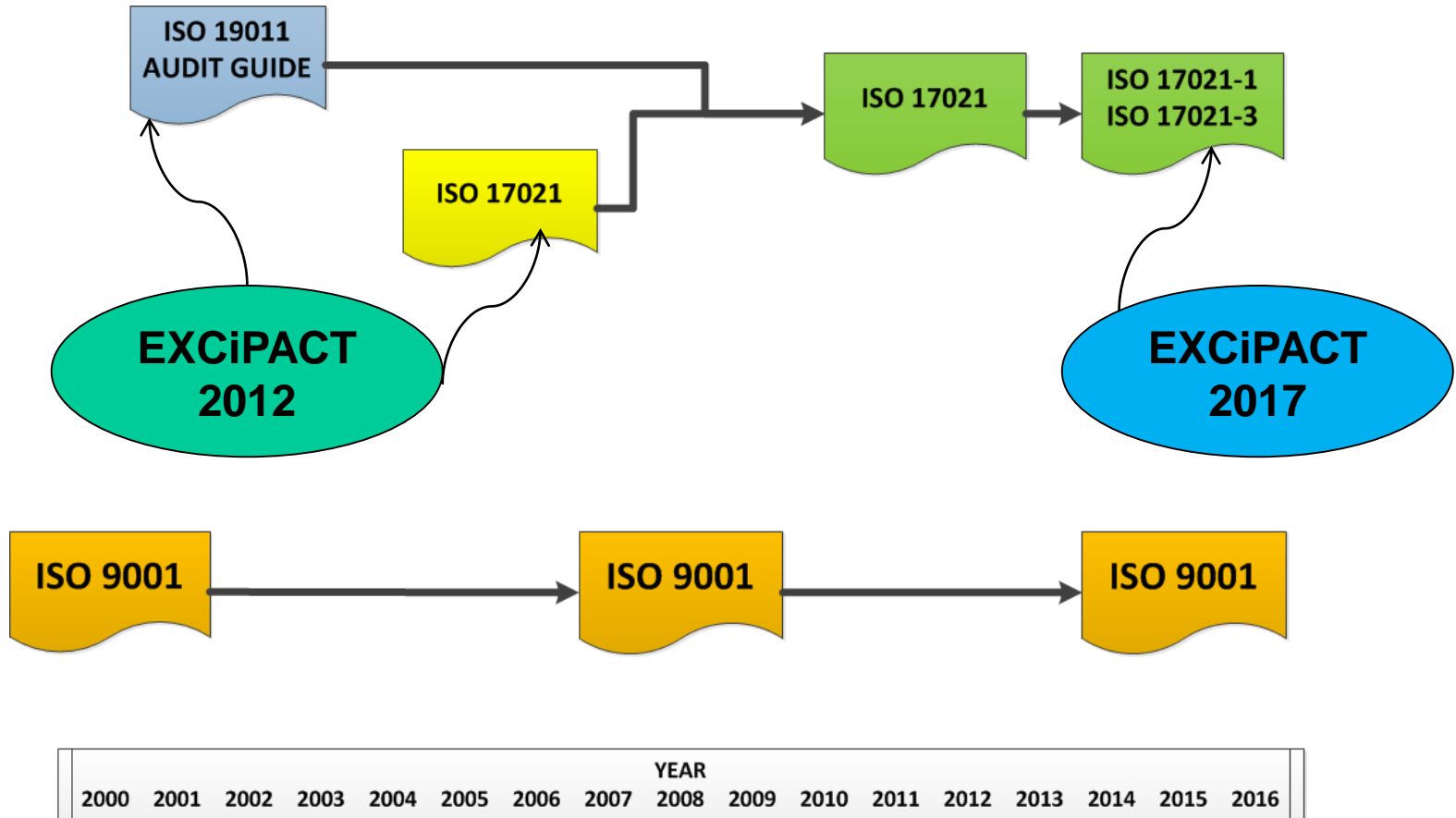


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# EXCiPACT Certification Scheme

## ISO Standards Update 2017

- Note: ISO Standard Development:



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## 关键指标/Key Performance Indicators 2013 – 2017

	2013	2014	2015	2016	2017 YTD
认证机构/Certifying Bodies	4	4	5	6	7
受认证公司/Certified Companies	5	13	25	48	58
审核员/Auditors	6	8	13	21	23

RE-CERTIFICATION - 3 YEAR CYCLE from 2016

Certifying Bodies 100%

Certified Companies 100% (except one)

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# ***EXCiPACT Global Certifications 2017***

## ***58 Certificates already issued in 15 countries:***

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



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## EXCiPACT Oversight / 监督

- [www.excipact.org](http://www.excipact.org) 网站上已报告有7家经注册的认证机构
- Certiquality Italy 是最新认证机构 – 注册于2017
- Blue inspection body和SGS 都开始了首个每3年成功的重复审核



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# EXCiPACT Oversight / 监督

- 截至2016年EXCiPACT的注册审核员
- 在中国已有3位
  - Leon Li, BV
  - Liren Wang, BV
  - Onnie Huang, SGS
- 2017 年会新增2位(见网站)



Name	Register Number	Country	Affiliation	Date issued
Stefan Kettelhoit	E0002	Germany	mdc (blue inspection)	20 June 2016
Norbert Waldöfner	E0003	Germany	mdc (blue inspection)	20 June 2016
Rod Combs	E0004	Germany	mdc (blue inspection)	10 June 2013
TS Shadagopan	E0009	India	SGS	20 June 2016
Meritxell Domingo	E0010	Spain	SGS	17 April 2014
Dietmar Barth	E0011	Germany	SGS	20 June 2016
Werner Kuhlmann	E0013	Germany	DQS	8 November 2013
Herbert Nagorski	E0014	Germany	DQS	9 March 2015
Carine Vandervorst	E0015	Belgium	SGS	25 April 2014
Christine Guilboud	E0016	France	Retired	26 June 2014
Bart Cole	E0019	Belgium	SGS	5 June 2015
Marion Boulanger	E0020	France	SGS	5 August 2015
Leon Li	E0022	China	Bureau Veritas Certification China	10 August 2015
Sophie Moreau	E0024	Belgium	SGS	19 October 2015
Michael Snella	E0025	Germany	AJA	15 January 2016
Liren (Irene) Wang	E0027	China	Bureau Veritas Certification China	28 January 2016
Véronique Balon	E0028	France	SGS	20 June 2016
Laura Moreno Baron	E0033	Spain	AENOR	10 May 2016
Raúl Blanco Bazaco	E0036	Spain	AENOR	14 July 2016
Martin J. Webster	E0038	USA	SGS	7 July 2016
Onnie Huang	E0041	China	SGS	21 October 2016

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# EXCiPACT 审核员的能力要求 /Auditor Competency

## EXCiPACT Auditor Training Course / 培训课程内容

- Mandatory for all EXCiPACT Auditors
- Next course in China to be held in 2018
- Course content
  - Where does GMP / GDP Start?
  - Writing observations (reminder of good auditing practices)
  - Classification of observations
  - Documentation which will be encountered in an excipient supplier
  - Compliance Issues – summary of tragic events and legislation, risk assessments
  - The EXCiPACT GMP and GDP Standards
  - Mock audit
  - Examination



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# EXCiPACT Certification

## EXCiPACT Future Plans

- Emphasis on the major excipient supplying regions
  - USA
  - China
  - India
  - Europe
- Aim
  - To get more organisations using the scheme
  - Better acceptance from users as part of their supplier qualification processes



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# EXCiPACT Certification

EXCiPACT Certification Scheme will not replace ALL pharmaceutical company audits BUT...

- Both Users and Suppliers of Excipients making more and more use of the scheme for mutual benefit without compromising regulatory compliance or patient safety
- Fully satisfies the EU Guidelines on ascertaining GMP/GDP for excipients
- Allows users to focus audit resources on the higher risk excipients
- Helps reduce costs for both suppliers and users by reducing the audit burden



# Benefit of EXCiPACT Certification to all stakeholders

- Excipient suppliers that hold an EXCiPACT GMP and/or GDP Certificate are a major asset to the excipient users
- Sharing the audit reports on a continual basis will ensure that not only are the needs of the initial risk assessment satisfied but also the continuing evaluation as well
  - A win for the supplier
  - A win for the user
  - A win for the regulator
  - A win for the patient





# EXCiPACT

## Reducing the Audit Burden

- **EXCiPACT asbl**

- is an independent, not-for-profit organization established in Belgium in 2014, with the following full members



The Pharmaceutical Quality Group



- **Impartiality is assured**

**[www.excipact.org](http://www.excipact.org)**

**Thank You!**



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L to R

Sarbari Roy (Novartis), Vice-President, (PQG), Joel D'Silva, Treasurer to 2016 (FECC), Joanne Blondiau (Secretariat), Kevin McGlue (Colorcon), President, (IPEC Europe), Carole Capitaine (Secretariat), Tony Scott, Head of Operations, (Consultant), Elisa Setién Treasurer from 2017 (FECC). Not pictured: Dale Carter (Huber), (IPEC-Americas)

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