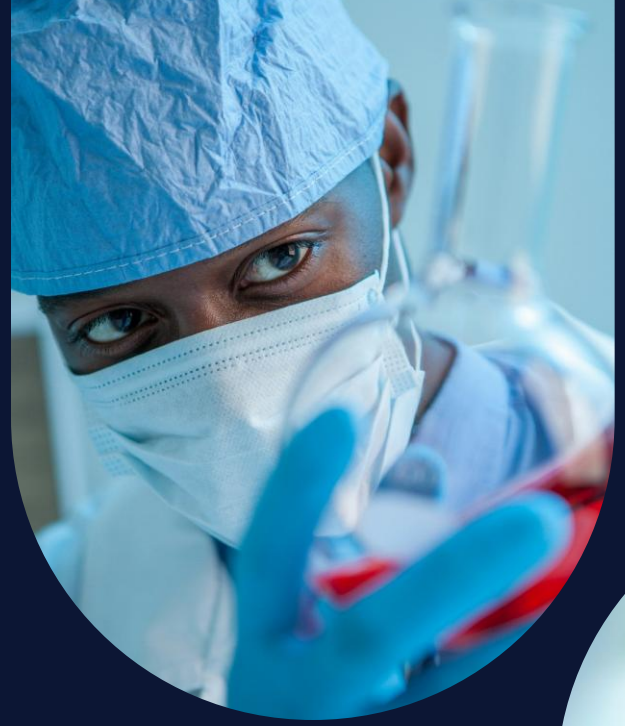
EXCiPACT™ TRUST CERTIFIED.





EXCiPACT 2025 Edition

Key Changes

Iain Moore, Senior Advisor Operations

On the agenda

- **Changes in the 2025 Edition**
- Other News

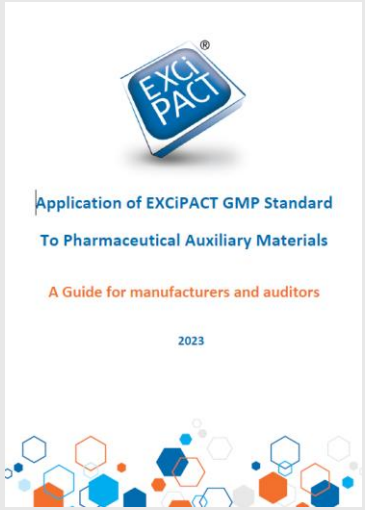


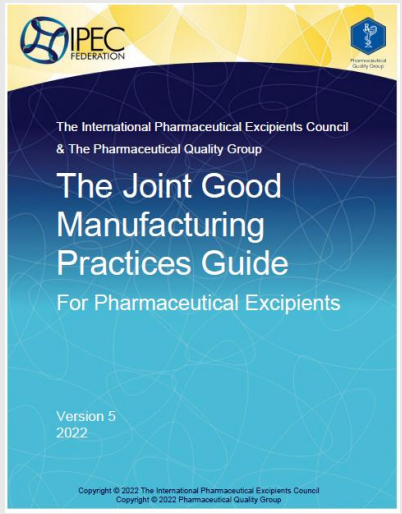


2025 Publication of EXiPACT Standards

- An update to the GMP, GDP and GWP Standards and the ISO 17021-1 annex was issued in July 2025
- The changes were minor overall and few new requirements were introduced.
- As the changes are limited Certificate holders will have 18 months to transition to the new standard:
- All recertification audits from 2027 will use the 2025 edition
- All certification audits will use the 2025 edition immediately







7.1.5.2 Measurement traceability

Where analytical primary reference standards are used, their approval, certification, storage and expiry shall be documented

In addition, the preparation and confirmation of prepared primary reference standards shall be documented.

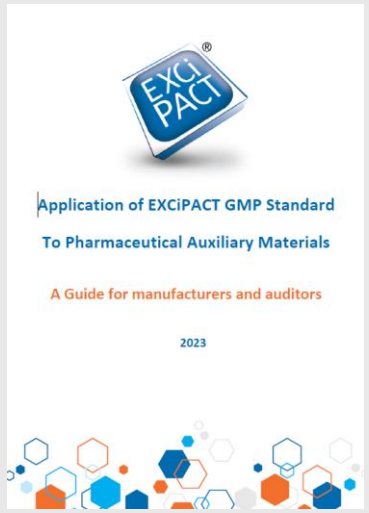
7.1.6 Organisational knowledge

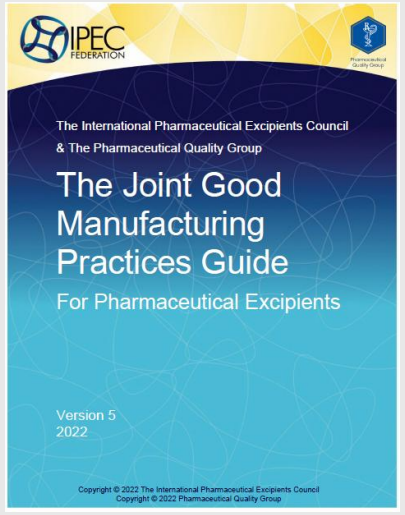
The organisation shall have knowledge of the regulations concerning the use of the excipients supplied, in the countries in which it is marketed taking note of the organisation's claims about the uses of the excipient.

Rationale for update

- Changes needed as a result of the issue of US FDA Warning letter to an EXCiPACT Certificate holder in 2022
  - Detailed rules for suspending and re-instating an EXCiPACT Certificate
- Alignment with IPEC-PQG GMP Guide 2022
- Alignment with USP draft <1078>
- General feedback from interested parties
- Inclusion of PAMs

- Changes in publication shown in orange text to aid identification and implementation







Key Changes

- Many changes made requirements explicit and aided translation into other languages
- Sterile excipients in scope (0.1)
  - Aligned with IPEC-PQG
  - Method of sterlisation to be communicated to customers
- PAMs in Scope
- Data Integrity made explicit throughout with ALCOA as the minimum expected standard required (4.4.3, 7.1.3, 7.3, 7.5.1)
  - Documented risk assessment to determine criticality of data (when to apply ALCOA principles)
  - Quality Unit responsibility to ensure compliance



Key Changes

- Clarifications
  - Excipient has to have a specification and be made to GMP (0.1)
  - Certification only possible if batches have actually been made (0.1)
  - Top management to ensure GMP objectives are periodically monitored and evaluated (5.0)
  - Risks to excipient quality now inlcude degradation not only contamination (7.1.4)
  - Pest control supplier approval and managed by defined persons (7.1.4.4)





Key Changes

- Clarifications
  - Change impact assessments to be documented and a note added that a decision to outsource activities would be a significnt change (6.3)
  - Water and cleaning agents added to example list of utilities that may impact excipient quality (7.1.3)
  - Quality unit to approve suppliers of cleaning agent, and those responisble for cleaning to be defined with which cleaning agent (7.1.4.4)







Key Changes

- Clarifications
  - Suppliers of reference standards to be approved, and the storage conditions documented, but if prepared internally the method to be documented and the means of confirmation recorded (7.1.5.2)
  - Knowledge of legislation required for the intended use in all countries in which excipient is marketed – also applies to distributors (7.1.6)
  - Repeated failures to created good entries in quality critical records to be dealt with as a non-conformity (7.5.2)
  - Traceability required both forwards and backwards – i.e. from customer to suppliers of raw mateials (8.5.2)



Key Changes

- Clarifications
  - Property provided by customers to be assessed as for any other delivered material, unless otherwise agreed or instructed by the customer (8.5.3)
  - Report required to show compendial methods have been verified alternatives validated. Where composite samples are used, evidence to be documented that the samples are representative. A confrimed OOS is to be dealt with as a non-conformity. COA to show OOS results (8.6)
  - Internal audit scope to include requirements in the EXCiPACT annex (9.2.1)





Key Changes

- Clarifications
  - Management review to include review of conformance to EXCiPACT standards, OOS and related analytical trends, and if significant changes were successful (9.3.1)
  - Evaluation if CAPA itself has to be managed as a significant change (10)





Key Changes

- Additional requirements
  - Outsourced activities to be risk assessed to determine criticality to quality and if critical to apply relevant aspects of EXCiPACT GxP requirements. To have written agreement the supplier will implement the GxP requirements and have evidence they have implemented these in their quality management system (4.4.3, 8.4)





Key Changes

- Additional requirements
  - Explicit deviation reporting procedure (7.4)
  - Details of tamper evidence seals to be shared with customers on demnd (7.4)
  - EXCiPACT audit reports to indicate if there have been regulatory inspections and what the outcomes were. Prohibition of the redaction of EXCiPACT audit reports (8.2.1)
  - Reworking requires a proactive risk assessment, and is classified as a significant change (8.7.1, 6.3)
  - Reprocessing to consider impact on excipient quality (8.7.1)





Key Changes

- Additional requirements
  - Recall procedure to be periodically tested, all interetsted parties proactively identified, and any actual recall notified to auditor at next EXCiPACT audit so it can be mentioned in the audit report. CB would also inform EXCiPACT (8.7.1)
  - Product quality complaints to be reported to the original manufacturer (GDP Annex, 8.7.1)





Other Changes

- Changes for Certifying Bodies (ISO 17021-1 annex)
- A critical NCN can arise from multple major NCNs (3)
- Pre-audits to be manged as any other consultancy (auditor cannot do it) (5.2.10)
- Multi-site certificates only allowed if sites within 10 mile (16Km) radius with the same top management (9.1.3)
- More than one auditor may be required when an audit to reinstate a certificate is conducted (may include a representative of EXCiPACT)(9.1.4)
- Multi-site sampling not allowed for GMP and GDP audits (no change) but can be allowed for GWP under stipulated conditions (9.1.5)





Other Changes

- Audit reports to include details of any
  - Recalls
  - Regulatory inspections and their outcomes
  - Method of sterilisation of sterile excipients
    - Note EXCiPACT would be notified of any recalls (9.4.8)
- Details of how to conceal propietary information in audit reports (9.4.8)
- Explicit requirements for re-instating a suspended EXCiPACT certificate, including witnessing by a representative of EXCiPACT (9.6.5.2)
- If Major or above NCNs raised by CB these to be reported to EXCiPACT (10)




Certification Standard for Pharmaceutical Excipient Suppliers
Good Manufacturing Practices (GMP)
Good Distribution Practices (GDP)
Good Warehousing Practices (GWP)
Requirements for Auditor Competency and Third-Party Organisation Providing Certification of the Management System
2025

Q&A

On the agenda

Changes in the 2025 Edition

Other News



- Two critical Questions
- Do pharmaceutical companies Accept EXCiPACT?
- Do healthcare regulatory authorities accept EXCiPACT?



- **Do pharmaceutical companies Accept EXCiPACT?**
- First question an excipient supplier hears from a potential new customer
- Have you got EXCiPACT?
  - Source: many excipient suppliers at CPhI Global 2024, 2025



- Do healthcare regulatory authorities accept EXCiPACT?

Feedback from EU Authorities

EMA Inspectors Working Group – Interested Parties Meeting March 2025 – emphasised that Drug Product Manufacturer has to qualify the Scheme Owner - EXCiPACT

MHRA, UK, April 2025 – same message, they see EXCiPACT acceptably used during inspections

Using EXCiPACT Certificates and Audit Reports is ok if

1. The Formalised risk assessment (FRA) indicates EXCiPACT GMP is suitable for that dosage form
2. EXCiPACT is qualified as a supplier

Acceptance of EXCiPACT Certification

- WHO – SMACs (Starting MAterial Certification Scheme) white paper explores idea that EXCiPACT Certification can have a role to play
- EDQM – you may use EXCiPACT Certificates as demonstration of the application of GMP in your Certificate of Suitability to the Ph Eur application
- USP – you may use EXCiPACT Certificates as demonstration of the application of GMP in your USP Excipient Verification Program application





Acceptance of EXCiPACT Certification

- Nigeria (NAFDAC) requires excipients to be made in an ISO 9001 or **EXCiPACT** registered facility







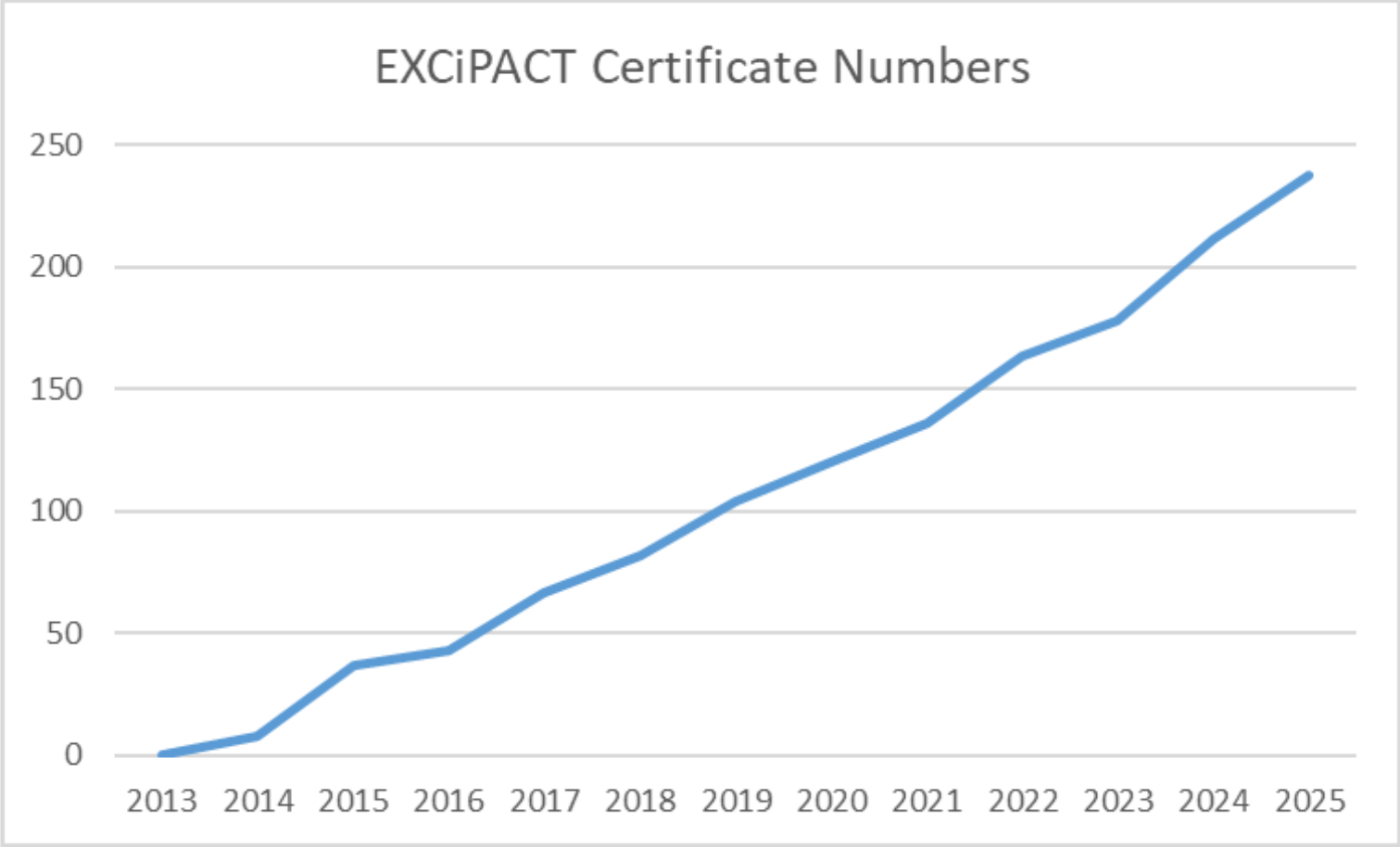




- Vietnamese regulations mention EXCiPACT as a suitable GMP standard
- India and Indonesia are drafting regulations for GMP for excipients, and these should mention the role of 3rd party Certification (like EXCiPACT)

Current EXCiPACT Certificates

- Critical Mass: 242 Certificates in place worldwide



EXCiPACT accelerating EXCiPACT GMP and GDP Standards



- EXCIPACT very suitable for excipients in low and medium applications (Formalised Risk Assessment)
- Covers the entire fixed supply chain (GMP, GDP, GWP)
- Independent oversight means it’s a certificate that is trusted by customers and the authorities

EXCiPACT™ TRUST CERTIFIED.

Thank you

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