EXCiPACT Auditors assessment

Results of the witness audit program to year 2026

Issue 1.0

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REC-20260809 – Witness audit results to Year 2026

1. Introduction

On August 26, 2024, EXCiPACT announced the project to reinforce the assessment of registered auditors: To have confidence in EXCiPACT audit reports and certificate decisions it is crucial that the EXCiPACT registered auditors who perform the assessments against EXCiPACT GxP standards are competent and have the same level of behaviour and scrutiny whatever the country and the certification body. EXCiPACT already requires that auditors are witnessed by a fully registered EXCiPACT auditor once every three years, but until this point, the witness has usually been another EXCiPACT registered auditor employed by the Certification Body (CB) who employs the auditor in question. Whereas this is the same process as used for ISO 9001 auditors, there is a small risk of a conflict of interest in this approach. For this reason, EXCiPACT began its programme of fully independent witnessing of registered EXCiPACT Auditors to compliment those performed routinely by the CB. This short report summarises the findings from the first two years of this programme.

EXCIPAT selected auditors in proportion to the number of certificates held by each Certifying Body, and by the geographical area in which the audits were performed.

The goals of the program of witnessed EXCiPACT audits are to:

- Witness at least one auditor from each Certifying Body in each region once every three years (the regions being Americas, Eastern Asia, Mid and Southern Asia, and Europe).
- The audits could be surveillance or certification/recertification
- Provide feedback and if necessary, re-training to auditors so that standards are maintained.

In each year a target was set to witness 7 auditors, and this was met in each year, despite the logistical challenges of getting a witness to a scheduled audit across the world.

2. Witness program

In the first year seven audits were planned to be made and completed by then of January the following year. In the second year, seven audits were planned to be made and six were completed. In addition, one audit was added in the program as the first audit made by another Certifying Body to fully qualify a new auditor.
To date, the overall witness audit program examined:

- Six audits from five different Certification Bodies in Europe
- Three audits from 2 Certifying Bodies in China
- Two audits from one Certifying Body in the USA
- One audit was witnessed in India

The assessment included the full audit process, from the preparation of the audit agenda to the audit report issuance and the CAPA plan review by the CB.

Findings were ranked according to the following scale:

- None
- Opportunity for Improvement (OfI) – individual coaching of the auditor is all that is needed
- Minor – formal coaching of the auditor is required within 3 months. A written record of the coaching and the reasons for it are held on the auditors record.
- Major – the auditor's EXCiPACT status would be suspended until it was demonstrated that the issue was addressed, understood. In cases defined by the Quality Manager, the auditor may require witnessing again to ensure the correct standards are applied during audits.

3. Witness Program Results

For seven audits, no significant observations were identified, and for the others, only opportunities for improvement were reported, as detailed in the following table:

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Audit #	Date	Region	Number Deviation	Number OfI
1	28/02/2025	India	0	1 *(see [a])*
2	30/04/2025	Europe	0	0
3	19/12/2024	Europe	0	0
4	16/01/2025	Europe	0	1 *(see [b])*
5	15/11/2024	Europe	0	2 *(see [c] & [d])*
6	08/05/2025	China	0	2 *(see [e] & [f])*
7	29/01/2026	Europe	0	1 comment (see [g])
8	24/03/2025	China	0	0
9	24/04/2026	China	0	0
10	07/05/2026	North America	0	0
11	12/05/2026	Europe	0	1 (see [h])
12	13/05/2026	North America	0	0
13	02/07/2026	Europe	TBC	TBC

The identified Opportunities for Improvement are as follow:

OfI [a]	The on-site duration during the audit was four hours for a two-days audit, i.e. less than 33% of the audit time
OfI [b]	The same auditor did audit the same client four successive times, which is against the recommendation of ISO-17021 and the internal CB's policies
OfI [c]	The same auditor did audit the same client for more than three successive times. It is recognized this also includes ISO-9001 certification audits
OfI [d]	During the audit, the auditor did not thoroughly question and clarify the systems and the processes
OfI [e]	The audit agenda indicated 2 hours on-site visit, to be compared to the full audit duration of four days. This has been corrected during the visit as audit of workshops and laboratories were made in detail, with appropriate shopfloor audit duration.
OfI [f]	The knowledge of the auditor related to pharmaceutical excipients topics may be improved (e.g. Pharmacopoeia knowledge, computerized requirements)
Comment [g]	When the audit program is changed during the audit, due to priorities and audit duration, this should be clearly mentioned to the auditee and also mentioned in the audit report.
OfI [h]	The time dedicated to on-site /shopfloor audit in the agenda is less than 25% of the total audit duration

4. CONCLUSIONS

This first survey of EXCiPACT-registered auditors did not identify any major issues and shows there are no significant differences concerning behaviours and competencies of the auditors, whatever their related certification body and their region.

Three Opportunities for Improvement are linked to the time spent at shopfloor audit, which is less than 30% of the audit duration. As a result, EXCiPACT will reinforce the requirement for a minimum audit time for the shopfloor examination to be not less than 30%, as mentioned in the Annex to ISO-17021 § 9.2.3.2. This would include time in the QC laboratories. It is acknowledged that for some small excipient suppliers, for example making one excipient using a simple manufacturing process that this target of 30% may not be achievable.

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Two OfI are linked to the fact that the same auditor did audit the same company for more than three times, which is not a best practice. However, it is recognised that in some regions there is not another EXCiPACT registered auditor available. EXCiPACT has therefore increased the number of scheduled auditor training courses to 6 per year, with at least one each year in each region.

After this programme, some other minor improvements were implemented by EXCiPACT:

- Name of related CB clearly mentioned in the witness audit report
- Time for shopfloor audit compared to full audit duration added in the EXCiPACT witnessing checklist
- Management of the audit agenda by the auditor, to be reported in the report
- The EXCIPACT witness reports are sent to the CB and to the auditor for information

These items have been communicated to all the EXCiPACT's CB and to the registered auditors during the periodic meetings and Continuing Professional Development training programmes.

Note:

This is a public summary of the report prepared by the EXCiPACT Quality Manager on this programme.

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