Explanation of the EXCiPACT Auditor Registration Process

Why individual auditor CVs are not required

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The EXCiPACT Auditor Registration Process

1. INTRODUCTION

Drug product Manufacturers are increasingly using EXCiPACT GxP Certification in the initial and ongoing qualification of their excipient suppliers. The corresponding records including the EXCiPACT GxP Certificates and audit reports form part of the evidence gathered about the GxP compliance of their excipient supplier. When this evidence is presented to the regulatory authorities during and inspection or as part of the drug product application process, they can be asked questions about the competency of the EXCiPACT auditors. Typically, this comes as a direct request for the auditor Curriculum Vitae.

This guide explains how EXCiPACT registers and qualifies the auditors who perform the EXCiPACT GxP audits and why EXCiPACT Auditor CVs are not made available.

2. AUDITOR REGISTRATION PROCESS

The full details for auditors to register with EXCiPACT can be found in the EXCiPACT Auditor Registration Scheme document which is available on the www.excipact.org website. There are full Auditor Competency requirements detailed in the EXCiPACT Standard "*Annex to ISO/IEC 17021-1:2015 for Certification Bodies*"

Prospective auditors are required to complete an application form which gathers the following evidence about their auditing competency.

To become an EXCiPACT Registered Auditor (ERA), the following requirements are compulsory, and evidence of attainment must be provided with the application:

Education & Auditing Experience

Auditors should have a tertiary education in a scientific discipline. Where a tertiary education has not been attained then substantial (>10 years) experience in relevant fields can be considered.

They should hold ISO 9001 Lead Auditor status and performed at least 2 years of audits to ISO or related standards. Whereas some GMP experience in these audits is desirable (e.g. Food GMP, Cosmetic GMP, Medical Device GMP), the critical requirement is they have auditing experience which leads to the issue of a Certificate that demonstrates the audited organisation is compliant to the requirements of the relevant standard. It is not uncommon for these auditors to perform over 50 such audits a year.

In addition, there is then a requirement for at least 5 years of work experience in the chemical sector. This is crucial because they need to recognise the hazards and risks to patients that may be present from the technologies and ways of working in the manufacture and supply of excipients. Although auditing experience in other business sectors will provide auditing experience and skills it is crucial to be familiar with the science, technology and ultimately the threats to quality in the excipient manufacturing and distribution sectors.

Evidence of the education qualifications and work experiences are shared with EXCiPACT in the application from the prospective auditor, usually in a Curriculum Vitae. This is held as a confidential record by EXCiPACT.

Competency in Excipient supplier auditing

Notwithstanding the ability of the auditor to perform ISO audits, and their experience in the chemical, excipient and related industries, all prospective auditors must also attend a two-day training course which is delivered by the EXCiPACT Quality Manager. This details the way EXCiPACT Certification works, and how it is built upon an ISO 9001 compliant management system. The way in which EXCiPACT uses risk assessments to define the specific GMP rules that are applied by the excipient supplier is also a key feature of the course.

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At the conclusion of the training course, there is a 3 hour open book exam which candidates have to attain a 70% pass mark.

However, this is not the conclusion of the process, as each candidate auditor then must be witnessed performing an EXCiPACT Certification audit. The witness is either another EXCiPACT registered Auditor or a consultant appointed by EXCiPACT (often the EXCIPACT QA Manager). The witness has to meet the same auditor registration requirements as the auditors.

At the conclusion of this process, the auditor will be fully qualified and added to the list of EXCiPACT registered auditors. This registration lasts for 3 years.

Continuous Professional Development and Reregistration

During the time EXCiPACT auditors perform audits, they are expected to accumulate at least 20 hours of continuous professional development, through attendance at relevant training courses etc. Each year EXCiPACT offers a 3 hour session to all registered auditors to introduce the latest developments in EXCiPACT Certification and to allow auditors time to share experiences and "hot topics" from the audits they have completed. EXCiPACT welcomes recommendations for topics to be included in these sessions.

At the end of their registration process, auditors need to submit their audit log detailing the EXCiPACT and other GMP audits they have completed. At this point the auditor register on the website is updated accordingly.

When an auditor retires or otherwise stops performing EXCiPACT audits, then their registration will show as lapsed. They will remain on the register for a period of time because existing audits done during the time they were registered will still be valid and excipient users may wish to verify the status of the auditor who delivered the audit report which has been presented by their supplier.

Reliance on Published EXCiPACT Auditor Register

This is a through and best practice approach to auditor qualification and registration. The requirements a fully detailed on the EXCiPACT website and in the EXCiPACT standard, particularly the Annex to ISO 17021-1 appendices.

In routine situations making the individual auditors CVs available would not add any additional value to those using EXCiPACT Certification or checking that it has been applied properly. Indeed, a full examination of the auditor CV is part of the EXCiPACT registration process. There would also be concerns of personal confidentiality and compliance with data protection regulations if auditors CVs were made available.

EXCiPACT always seeks to apply best practices to ensure EXCiPACT Certification auditors are competent, impartial and objective.

3. REASON FOR REVISION

No changes to original, other than placed into an approved template and assigned a document number.

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