



## **Recommendations for Participants of the Internal Audit Exchange Program (IAEP)**

The following recommendations are offered to the participants of the Oregon Bioscience Association's Internal Audit Exchange Program (IAEP)—both for the organization being audited (“host company”) and for the auditor—to better ensure a smooth exchange.

### **Host Companies**

- Review your internal audit procedure to make sure that the exchange auditor can audit your system. Consider the need to modify your internal audit procedure to allow for external auditors.
- Review your company's legal and business policies to determine if a confidentiality agreement or non-disclosure agreement is required. Some companies may not require this level of control. Remember, the IAEP is designed so that no money is exchanged between participating companies.
- Request the appropriate background information, educational, and training experience of the IAEP auditor to meet your internal audit procedure requirements.

Examples of auditor qualification include, but are not limited to, the following:

- ASQ certification (CQE, CQA)
- RABQSA, IRCA, or similar auditor training/certification
- FDA experience as an investigator/inspector
- Registrar experience as an auditor
- Medical device quality system auditing experience

Maintain these auditor qualification records to show to your customers and/or third-party auditors.



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- Supply your IAEP auditor with your internal audit procedure and appropriate forms.
- Consider whether the IAEP auditor needs to review any previous audit findings in preparation for this specific audit.
- Schedule the audit to meet your internal audit schedule.
- Discuss with the IAEP auditor the elements of the standard(s), regulation(s), or company processes to be audited. It is recommended that the host company identify one or two small systems that require no more than one eight-hour audit day with the addition of audit preparation and audit write-up.
- If a written audit plan is required by your internal audit procedure, discuss its format with the IAEP auditor, and get an agreed upon date with your IAEP auditor when the audit plan is needed by. This will help you in making sure you have the proper personnel available for the IAEP audit.
- Provide the IAEP auditor with your company's internal audit checklist or agree on a separate format to be used for the audit.
- If there are any safety issues or cleanroom protocols relevant to the audit, discuss with the IAEP auditor prior to the audit day or on the audit day, as applicable to the situation. Some of these safety procedures may require a short training be documented.
- Provide lunch for the visiting auditor.
- Host companies conduct their own verifications that any audit findings have been addressed. That is, IAEP auditors are not responsible for subsequently closing out corrective actions that resulted from their audits.
- Call or email [iaep@oregonbio.org](mailto:iaep@oregonbio.org) to report that an exchange audit took place at your organization.



## **Auditors**

- Submit your audit checklist, audit notes, and audit report to the host company within the agreed upon timeframe. Note that you may be asked to write and sign an audit report cover letter stating the audit date, the standard(s)/regulation(s) used as the audit basis, and the elements that were covered. This cover letter would not give any indication of the audit findings since internal audit results are not shown to regulatory bodies.
- Your audit report will follow the requirements of the host company's internal audit procedure or an agreed-upon deviation from this procedure, but should, at a minimum, include a list of the areas/processes audited, the elements of the standard/regulation covered, the audit date, the audit findings (nonconformances, observations, recommendations), your name and company, and should be signed by you.
- If you would like to get credit for the internal audit towards an auditor certification program, discuss this with the host company prior to the audit. You would be responsible for preparing the necessary audit acknowledgement letter or form for signature by the host company at the time of the audit.
- Call or email the Oregon Bioscience Association to report that you conducted an exchange audit.

## **For All IAEP Participants**

- If you are willing to have a trainee auditor "shadow" the working auditor for the purpose of learning the auditing process firsthand, discuss this up front with the company you are partnering with on this audit. (The trainee auditor may be from the host company, the auditor's company, or even another IAEP participating company.)