The proposed template appears to expect the QP to personally audit the manufacturing site where the IMP is manufactured or alternatively attend an audit conducted by a third party. Otherwise a justification is required if either of the former cannot be met.

Currently the QP in Europe will accept an audit report on an IMP site that was performed by a third party audit team. A QP would not perform or attend the audit.

What is the requirement for a QP to attend a third party audit? Gilead feels as long as the auditors are appropriately qualified to audit a particular facility and the QP has access to the resultant audit report, this is sufficient.

Given the expectation in the draft template for QPs to attend all audits, Gilead feels that the resource demands on any organisation is unreasonable.