The value to blood establishments of supplier quality audit and of adopting a European Blood Alliance collaborative approach

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Background. The assessment of suppliers of critical goods and services to European blood establishments is a regulatory requirement proving difficult to resource. This study was to establish whether European Blood Alliance member blood services could collaborate to reduce the cost of auditing suppliers without diminishing standards.

Materials and method. Five blood services took part, each contributing a maximum of one qualified auditor per audit (rather than the usual two). Four audits were completed involving eight auditors in total to a European Blood Alliance agreed policy and process using an audit scope agreed with suppliers.

Results. Audits produced a total of 22 observations, the majority relating to good manufacturing practice and highlighted deficiencies in processes, procedures and quality records including complaints' handling, product recall, equipment calibration, management of change, facilities' maintenance and monitoring and business continuity. Auditors reported that audits had been useful to their service and all audits prompted a positive response from suppliers with satisfactory corrective action plans where applicable. Audit costs totalled € 3,438 (average € 860 per audit) which is no more than equivalent traditional audits. The four audit reports have been shared amongst the five participating blood establishments and benefitted 13 recipient departments in total. Previously, 13 separate audits would have been required by the five blood services.

Discussion. Collaborative supplier audit has proven an effective and efficient initiative that can reduce the resource requirements of both suppliers and individual blood service's auditing costs. Collaborative supplier audit has since been established within routine European Blood Alliance management practice.

Keywords: blood establishment, audit, supplier, quality assurance, system.

Introduction

The European Blood Alliance (EBA) is an alliance of European Blood Services whose aim is to contribute to improvements in the safety, security and cost-effectiveness of blood, tissues and cell supply through encouraging collaboration among European blood and tissue services. The EBA comprises 23 European Union (EU) and European Free Trade Association (EFTA) Blood Services[1]. The EBA's Benchmarking Group has identified a wide range of purchased goods and services during the collection, processing, testing and issue of blood and tissues and in the provision of diagnostic services with opportunities to collaborate in the specification and procurement of these supplies[1,2].

The term "critical supplier" (supplier of "critical material" or services) is applied to those suppliers whose goods and services can affect the quality and availability of a blood service's therapeutic products, its diagnostic services or otherwise affect the safety of patients, donors or staff[3]. Examples include suppliers of blood bags, *in vitro* diagnostic medical devices and information technology (IT) systems. The assessment and approval of critical suppliers is a requirement of quality standards implemented by European Blood Services within their blood establishments including Blood Safety Directives[3,4], Good Pharmaceutical Manufacturing practice[5] (GMP) and Medical Laboratories - Particular requirements for quality and competence[6]. Understandably, requirements fall short of prescribing specific method(s) and frequencies, instead inferring that these should be selected using a risk-based approach[7]. Methods of supplier assessment typically include: questionnaires; confirmation of quality certification, for example ISO

9001[8] and ISO 13485[9]; obtaining references from other customers and the quality audit of manufacturing and distribution sites[10]. For suppliers of critical goods and services, the latter approach has become the norm for the nine EU Blood Services represented on the EBA Work Group on Collaborative Validation (WGCV) [*EBA unpublished finding*].

To be of value, a supplier audit needs to fulfil a range of criteria: audits should be carried out as a prerequisite to an award of contract and at defined intervals thereafter in a risk-based approach[7,10]. Audits should be performed by suitably qualified and experienced auditors to defined standards and a scope agreed in advance between the blood service and supplier's representative (auditee)[10,11]. Audit findings need to be classified in accordance with their severity, referenced to applicable standards, verified with suppliers and then promptly reported[10]. The audit report should prompt a corrective and preventative action (CAPA) response from the supplier describing the actions that will be taken together with timescales for their completion (that should be in accordance with the severity of the finding)[10]. The CAPA response should be reviewed and approved by the auditor(s) and tracked to completion and closure of the audit. In some circumstances, additional audits may be required to follow up and verify CAPA[10].

The scope of a supplier audit will generally be prepared to answer a number of questions ultimately aimed at providing the blood establishment with assurance that the supplier will work in partnership to consistently deliver goods and services of the required quality[11]. Questions fall into the following broad areas:

- has the supplier implemented a quality assurance (QA) system appropriate to the activities being carried out and, when applicable, registered this to the relevant quality standard(s)?
- are the suppliers' manufacturing and distribution activities in accordance with the principles of GMP, especially concerning the suitability and maintenance of premises/facilities, supply of sterile products, maintenance of the "cold chain" for labile products and maintenance of traceability?
- does the supplier have sufficient resources available, including trained staff and "state of the art" equipment to take on the contract without compromising quality?
- has the supplier been prompt in responding to complaints and concerns and, where necessary, in effectively implementing any required CAPA?
- has the supplier managed and communicated change effectively?
- does the supplier have robust plans to ensure continuity of services in the event of an emergency/ disaster affecting premises, equipment and staff?

The planning and completion of a programme of supplier audits by each of the nine participating blood services represented on the WGCV was, given the extensive range of critical goods and services used by these services, understandably found to be complex, costly and difficult to resource with suitably qualified and experienced staff. Many of the commonly used critical suppliers to European blood services operate globally with a distribution network throughout Europe and with manufacturing bases outside of Europe including the United States, Mexico, China, India, Japan and the Caribbean. Although differing from country to country in their precise utilisation (depending on prevailing contractual arrangements), when viewed across the EBA, a "core" of critical suppliers is in use by multiple European blood establishments. In a more limited number of cases, the critical supplier's activities are confined to one country, for example donor "call up" and provision of printed/label materials.

The audit of a critical supplier to a blood service traditionally involves a qualified lead auditor with specialist knowledge of quality management systems and a second auditor with specialist scientific/technical knowledge of the supplied product or service and takes a total of 1 to 3 days depending on the supplier's location. Audit arrangements/ administration, formal reporting, CAPA follow-up and audit closure typically account for a further day of the lead auditor's time. A typical audit workflow is shown in Figure 1. Supplier audits typically cost participating EU Blood Services between € 500 and € 3,500 depending on the supplier's location and the audit scope (which is dictated by the range and complexity of suppliers manufacturing and/or distribution activities and processes).

The challenge experienced by collaborating EBA members in funding and staffing a full programme of supplier audits prompted the EBA Work Group on Collaborative Validation to establish a Collaborative Supplier Audit (CSA) sub-group in 2010 to assess the feasibility of collaborative audit through a pilot study. This follows a previously successful initiative (EUBIS) to help standardise inspection/audit methodology for EU blood establishments[12,13].

The aims of the EBA CSA pilot study were: to identify EBA member blood services and their staff representatives that wished to collaborate on the auditing of critical suppliers; to identify critical suppliers that were used in common by collaborating EBA members; to identify valuable retrospective audit reports from suppliers audited during 2010 that might be shared between collaborators (with the suppliers' agreement); to define an EBA collaborative supplier audit policy, process and procedure and to collaborate in the planning, completion and reporting of prospective audits of five critical suppliers used in common by collaborating EBA

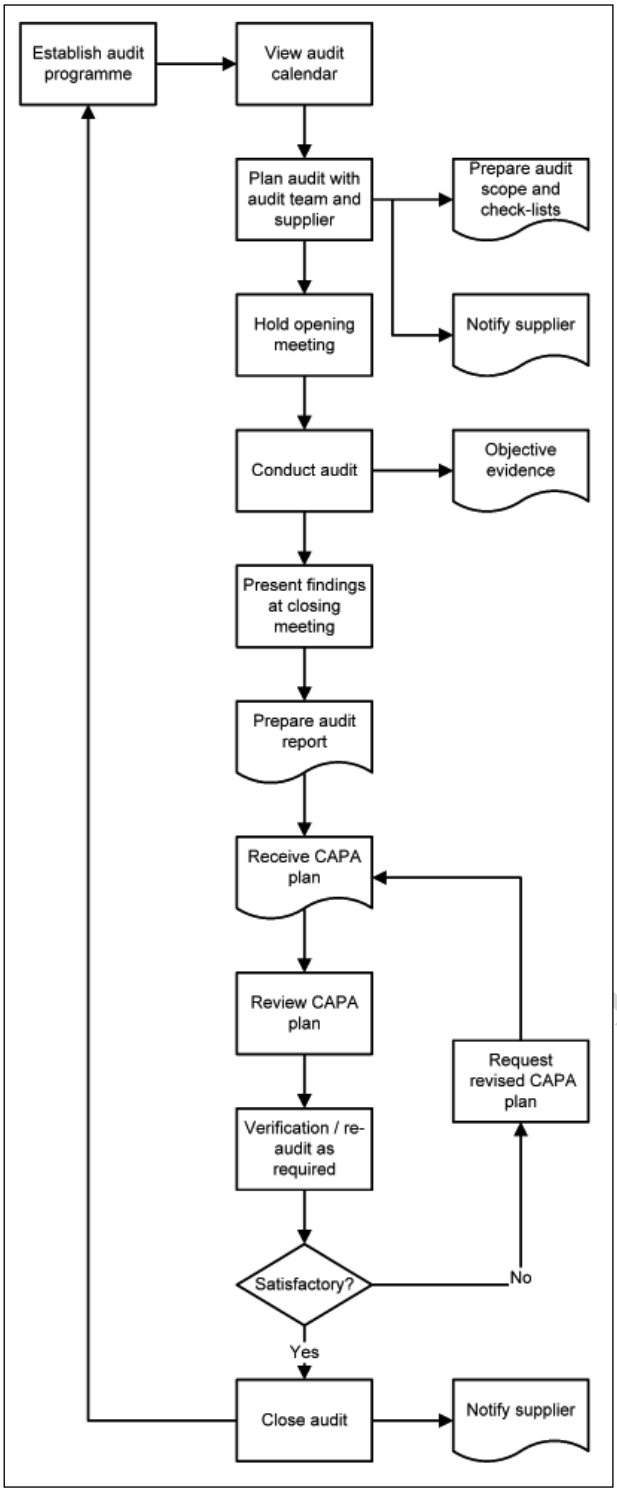

Figure 1 - Supplier audit workflow.

members. The overall objective was to establish whether EBA members working in collaboration could reduce the cost of funding their audit programme to the same standard and to reduce the burden on suppliers imposed by multiple audits from EU blood services.

Materials and methods

Constitution of a collaborative supplier audit workgroup

The EBA Executive Board approved in principle a CSA initiative during 2010 and invited interested blood establishments to participate. These included the French Blood Establishment (EFS), France; National Health Service Blood and Transplant (NHSBT), England; Rodekruis Blood Service, Belgian-Flanders; Sanquin Blood Supply, the Netherlands, and the Scottish National Blood Transfusion Service (SNBTS). Each blood establishment contributed a member of QA personnel involved in managing and participating in their national supplier audit programme. A representative was assigned on behalf of the EBA to coordinate, document and report activities.

Documentation

The CSA workgroup established its *modus operandi* during an initial meeting in 2010 and agreed a policy (Table I) that would ensure each blood establishment contributed to, benefitted from and was in control of the CSA process. The group designed and documented a process for identifying potential audits, arranging, conducting and reporting the audits and following up on any CAPA with suppliers. Draft audit scopes for suppliers of medical devices and *in vitro* diagnostic medical devices were agreed and a classification system was defined for observations made during the audit including their severity (Tables II and III). An audit programme was drawn up based on a review of critical suppliers used by each contributing blood establishment and their future audit requirements.

Planning and conduct of collaborative audits

Five supplier audits were scheduled for the pilot trial to be completed in the last quarter of 2010 and first quarter of 2011. Audits were decided for a manufacturer of blood bags, a distributor of blood bags and sterile

Table I - EBA policy on the completion of collaborative supplier audits.

Each blood establishment will retain control over the evaluation and selection of suppliers, risk assessment, audit planning, completion and closure of audits.
Sharing of audit resource will only occur with mutual consent of the blood establishments.
Prior agreement of audit standards, criteria, process and procedures.
Each blood establishment may lead or be involved in an audit irrespective of the supplier's location when their Service considers it necessary.
Cost of auditing is shared among the members that wish to audit and/or receive the report.
Onus is on the recipient(s) of individual audit reports to fund any translation costs.
Collaborative audit procedural documentation would eventually be available to blood establishments in their first language.

Table II - Risk-based classification of audit observations.

Non-conformity. The non-fulfilment of a standard, regulatory requirement (the standard/clause must be referenced in the audit report):
Critical. Has a direct impact on the health and safety of people (patients, donors, staff or members of the public), product and/or service quality, results delivery, the environment or the continuity of the service or product provided;
Non-critical. Has an indirect impact on the health and safety of people (patients, donors, staff or members of the public), product and/or service quality, results delivery, the environment or the continuity of the service or product provided.
Observation. A fact (concern) which is emphasised by the auditors, which if not addressed might become a non-conformity or result in the failure of the product or service in future. (The supplier is also required to respond to observations.)
Suggestion for improvement. A way identified by which the supplier can progress.
Comment. Other significant information that may be of value to the supplier or Blood Service(s).

Table III - Example of an audit scope.

Opening meeting
Introductions
Audit scope, time-table/arrangements
Confidentiality agreements
Reporting arrangements
Organisation structure and staffing (overview)
Licensing/accreditation and certification
Quality system with particular reference to procedures for:
Internal corrective and preventative action
Internal and supplier audit
Change control and validation
Document control
Staff training
Customer comments/complaints' handling
Market surveillance
Reporting of incidents to competent authorities
Advisory notice issue
Product recall
Management quality review
Site tour/orientation
Security
Environmental control of manufacturing and storage areas
Manufacturing process
Starting materials' selection and goods' inwards inspection
Reagent standardisation/quality control
Manufacturing procedures and "in process" quality control
Equipment calibration and planned preventative maintenance
End-product quality control/release
Delivery of test kits and after sales
Consignment labelling, packaging, transport, audit trail, control and monitoring of the transport times and temperature.
Detection, notification and handling of non-conforming deliveries.
Technical support arrangements.
Emergency planning/disaster recovery
Closing meeting
Introductions, acknowledgements
Audit findings
Questions/clarifications
Corrective action/close-out arrangements

tube welding devices, a manufacturer of microbiology reagents, a manufacturer of nucleotide amplification technology for blood-borne virus screening and a manufacturer of blood grouping equipment and reagents. Participating blood establishments contributed a lead auditor, qualified through the International Register of Certified Auditors (IRCA)[14]. Additional trained auditors were also assigned as determined by the audit scope and with knowledge of the purchased product or service. Suppliers representatives (QA Managers) were contacted by the lead auditor assigned to each collaborative audit. The audit scope and date agreed were agreed and any confidentiality agreements requested by the supplier completed. The lead auditor helped coordinate the audit team's arrangements including travel and accommodation leading up to the audit. The planning, communication with suppliers and the audit team, coordination of activities and preparation of the audit scope involved the lead auditor (a senior manager) in approximately half a day's work in total.

Each audit commenced with an opening meeting for introductions and to confirm the audit's scope, standards and supplier's detailed programme accommodating the scope. The audit team ranged from one to three members and took either 1 or 2 days to complete depending on the supplier's location and the audit's scope. The number of auditors assigned and time spent completing each of the four audits is shown in Table IV. The supplier provided an audit guide(s) sharing a common language with the auditors who accompanied the audit team throughout. The audits were conducted to cover the scope shown in Table III. Observations, classified according to Table II, were noted and verified with the guide during the audit. When necessary the auditors separated to ensure full coverage of the scope. A closing meeting was held to report findings verbally, discuss any matters arising and confirm arrangements for reporting the audit and the supplier's CAPA response when necessary. Following each audit, the lead auditor produced, within 20 working days, a written report acknowledging the supplier's contribution, identifying examples of good practice, any non-conformities and opportunities for improvement observed and additional comments with information of use to the supplier and/or blood establishment. Where required, CAPA plans were received from the supplier within 28 days detailing their proposed corrective and preventative action in response to each non-conformity and observation and giving the time-scale and responsibilities for completion. The lead auditor reviewed these actions with the audit team requesting additional information when necessary and finally closed the audit when satisfied that appropriate action had been taken. The preparation of the detailed audit report and time spent following up and closing each audit occupied the lead auditor on average for a further

Table IV - Audit resources and findings.

Audit ID	Supplier/activity audited	Suppliers activities previously audited by collaborating blood services?	Number of auditors assigned to audit	Number of days spent auditing	Number of observations	Observations
1	Blood bag manufacture	Yes (not at this site)	1	1		No corporate business continuity plans; "in process" checks on water not completed; environmental monitoring records incomplete; excess labelled packaging not reconciled; osmolarity control limits not correctly established; records of blood bag testing to ISO3826-1 not available during audit.
2	Manufacture, storage and distribution of bacteriology reagents for environmental monitoring. Manufacture of raw materials (antigens and antibodies) for virology assays manufactured at other sites. Storage and distribution of ready for use virology and microbiology reagents.	No	2	2		No corporate business continuity plans; production environment unsuitable during renovation; product recall procedure and handling deficient; complaint procedure and handling deficient; missing status labelling from withdrawn equipment; unlabelled reagents; shipping procedure not documented, audited or adequately recorded; hard copy standard operating procedures not copy-numbered; no records of production losses/ CAPA; some reagents not traceable in batch production record.
3	Blood bag storage and distribution. Blood component processing equipment sales and service.	Yes (2 previous audits)	3	1		Measuring equipment not calibrated; complaints procedure not followed; supplier's subcontractor not identified; product specification not referenced in service level agreement; missing batch release criterion for consumables; line clearance not documented.
4	Manufacture, storage and distribution of nucleotide amplification technology for blood-borne virus screening.	Yes (1 previous audit)	2	1	0	None

half day. Audit reports and CAPA plans were shared between EBA members contributing to the pilot study within the bounds of any confidentiality agreements. The cost of each auditor's participation was calculated as the sum of their travelling, accommodation and subsistence expenses in travelling to and from the audit site for the duration of the audit. The total and average cost of the four audits was also calculated from the overall sum for all participating auditors.

Results

The EBA policy on collaborative supplier audit was founded on the principles in Table I.

Four of the five planned audits were completed (the manufacturer of blood bags, the distributor of blood bags, the manufacturer of microbiology reagents and the manufacturer of nucleotide amplification technology). The audit of the blood grouping equipment and reagents supplier was not completed as a part of this pilot trial owing to resourcing issues. All sites audited were within Europe.

The four audits revealed a total of four critical (major) non-conformities, eight non-critical (other) non-conformities and ten opportunities for improvement. The number of observations and activity/process to which they related is shown in Table IV. Concerns included deficiencies in processes, procedures and quality records concerning handling of complaints, product recall, equipment calibration, maintenance of clean rooms, environmental monitoring, maintenance of the "cold-chain" (2 °C to 8 °C) during the transport of *in vitro* diagnostic medical devices, management of change to the production environs and documented emergency planning/disaster recovery arrangements.

Auditing of the complaints procedure by tracing examples of complaints registered by EBA members was especially valuable in two audits revealing non-conformities ranging from failure to record the complaint, failure to take timely and effective corrective action (mediated through root cause analysis) and failure to report findings to the blood establishment. Other observations were deficiencies in the management of change associated with renovation of areas adjacent to production clean rooms and the requalification of a clean room which lacked risk assessment, adequate containment, enhanced monitoring and cleaning and a timely management review. In several cases production processes lacked adequate "line clearance" and reconciliation of materials, especially those used in the labelling of products. Inadequate reconciliation

also applied in one case to a product recall which lacked an assurance that all manufactured products had been accounted for and in another case caused a significant delay in closing the recall. Failures of traceability included status labelling missing from equipment withdrawn from use, missing calibration status, unlabelled reagents and reagent details missing from batch production records. Failures to calibrate critical instruments were rare with the occasional overdue item. Internal and suppler audit programmes were well organised with schedules adhered to and CAPA implemented, when necessary, within prescribed and realistic time-scales. Documentation was generally comprehensive including standard operating procedures with ample coverage of production and quality control processes and associated training records. The documentation of emergency plans was highly variable. Two suppliers had made a detailed analysis of all factors that might influence the company's ability to recover from a range of emergencies/disasters while the other two had apparently made no consideration at a corporate level.

The majority of observations (16/22) were, unsurprisingly, registered for suppliers' activities and sites audited for the first time. All four audits have been reported to suppliers and satisfactory corrective/ preventative action plans received.

The total cost of completing the four audits was € 3,438 with an average cost of € 860 per audit. The cost for each participating auditor ranged from € 360 to € 786 depending on the location of the supplier and auditor. Taking the ratio of audits completed to reports received by the five participating services (13 so far), this represents a potential efficiency saving of at least 3:1 which will increase dependent on further request for the audit reports. Given an effective mechanism for cost-sharing this would effectively bring the cost down to € 264 per audit. The CSA groups worked cost effectively with all meetings held by audio conference.

Six auditors were involved in the pilot trial and responded to a post- audit survey. All concluded that the audit was useful to their blood establishment and five out of six considered that its scope and coverage achieved their objectives. The sixth auditor reported some difficulty in accommodating their national audit requirements within the collaborative audit plan that could be resolved in future by a slightly longer audit. Auditors responded with a mix of positive comments, some serious reservations and suggestions for improvement, as shown in Table V. In particular, Table V highlights the challenge of encompassing the auditors' dual requirements of a supplier audit. Firstly in ensuring that suppliers are meeting their regulatory and registration requirements, for example in having a robust quality system conforming to ISO13485 and GMP compliant processes and facilities. Secondly, in ensuring, where relevant, that specific national contractual requirements (for example, specific production, service and performance requirements) are met. This is less of an issue when EBA common purchasing specifications and contractual frameworks apply (see discussion). No concerns were raised by the regulators/competent authorities of the countries involved in this initiative (see discussion).

Discussion

An analysis of the findings of the four collaborative audits indicates that the majority of deficiencies were in failing to address the requirements of good manufacturing practice adequately[5]. Each company was registered to ISO 9001:2008[8] and there were understandably very few non-conformities against this standard, given the regular "notified body" external audit associated with registration. For medical device and *in vitro* diagnostic medical devices manufacture, ISO 13485:2003[9] although overlapping with GMP, does not address the wide ranging and detailed coverage of the requirements for premises, facilities, manufacturing and quality control included within GMP. Suppliers commented that the auditors focus on GMP had brought a valuable perspective to these supplier audits.

Potential advantages of collaborative audit include: substantial savings in audit costs and auditors' time commitments for EBA members; ability to audit suppliers not previously visited (owing to location and/ or cost); more extensive and immediately available information on a supplier's quality system, facilities and compliance issues with which to vet prospective suppliers (where auditing often lies on the "critical path"

Table V - Auditor feedback following collaborative audits.

The audit experience lacked "customer focus" and needed to avoid a "certification-like" approach to add value to the supplier's own certification audit.
There was also some difficulty in accommodating each auditor's national contractual requirements (and not just shared points of interest) in the collaborative scope. As a consequence not sure if it will save recourses.
Need clarity in defining the goal of EBA audits in covering general GMP/ISO/European legal requirements rather than country-specific tender etc. requirements.
Size of the audit team can be too unwieldy, possibly restricting audits to a maximum of two auditors per team.
Produce an EBA standard audit report template (rather than the usual report of the lead auditor) and possibly make the reporting requirements and audit plan more detailed.
Provide a central access controlled EBA database of audit reports, templates and suppliers' background information.
Provide a prospective and legally sound confidentiality agreement mechanism to ensure that audit reports can be freely circulated within the EBA when a supplier requests written confirmation (possibly more of a concern regarding disclosure to competing suppliers).

for procurement activities); assisting the EBA in joint procurement of harmonised critical supplies (medical devices and *in vitro* diagnostic devices); and more likely availability of auditors speaking the language of the site in question. All of these points can be potential areas for concern for traditional supplier audits completed by a single blood service, especially with the added time pressures imposed during tendering with multiple shortlisted suppliers.

Collaborative supplier audits proved an attractive proposition to suppliers who are required to host multiple, senior management resource intensive audits. Potential disadvantages include a missed opportunity for each blood establishment to see "first hand" the supplier's processes and better understand the quality issues that might arise. It may, therefore, be inappropriate for a blood establishment to exclude itself from this process entirely, especially before award of contract to a new critical supplier. There were also some initial concerns from a regulatory perspective over delegating this responsibility to a third party. These concerns have not been substantiated by the EBA members participating in this initiative, nor in subsequent EBA collaborative audits. As a precaution, however, EBA members who are concerned by this aspect should take advice from their competent authority.

Collaborative audit is a potentially highly cost-effective initiative that can be applied when two or more EBA members share a common supplier. Of the four audits completed, no blood establishment contributed more than one auditor (typically two would be involved). The four audit reports produced have so far benefitted 13 blood establishment recipient departments. Previously, 13 separate audits would have been required by the five blood services. The pilot study has demonstrated that CSA can be completed to a satisfactory standard, especially if the reservations and suggestions for improvement noted in Table V are addressed.

Regarding concerns over "customer focus" this is typically ensured by auditors taking examples of their current or unresolved customer complaints and recent change requests to determine progress or where deficiencies lay. Provision of a central access controlled EBA database of audit reports, templates and suppliers' background information could readily be achieved using the EBA's Basecamp software. The EBA is taking legal advice concerning confidentiality agreements and in particular to ensure that circulation of reports to EBA members does not breach such arrangements with suppliers. An apparent solution for future audits is for an EBA representative to enter into such agreement on behalf of all of its members prior to the audit.

There are certainly issues around audits concerning national contracts to ensure that each blood establishment's areas of interest and concern are incorporated into the audit scope. This will always require careful negotiation and an empathetic approach in drawing up the scope, if necessary allowing additional time during the audit to cover all participants' concerns. Encouragingly, however, the EBA CSA initiative has since extended into the procurement of Eurobloodpack. This joint EBA member initiative with a common purchasing specification[2] and contractual framework has enabled the six EBA blood establishments involved to readily agree a common audit scope for blood pack suppliers. Three further collaborative audits for Eurobloodpack have since taken place, two of which have been outside of Europe making this collaboration an extremely economical option.

The EBA's novel approach to CSA has probably been implemented for the first time by European Blood Services. This initiative has been demonstrated to be highly cost-effective and efficient and, in the experience of pilot sites, able to reduce the cost and time spent auditing shared critical suppliers to at least one third of the current levels. Since the pilot, CSA has become well established within routine EBA management practice and is realising these savings for additional blood services. Suppliers involved to date have taken a positive approach to the initiative and responded promptly with robust CAPA where appropriate to improve their quality systems, facilities and processes. A programme of collaborative supplier audits capable of identifying issues such as those in Table IV when coupled with prompt and effective CAPA by committed suppliers therefore has the potential to improve the quality of goods and services offered to EBA members significantly.

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